Population Council Program III
HRN-A-00-99-00010

Final Program Report

13 August 1999 – 31 August 2005

January 2006

CONTENTS

GLOSSARY

Population Council Program III (PCP3). USAID Cooperative Agreement HRN-A-00-99-00010 with the Population Council.

Activity. Sometimes also referred to as a project. Each program consists of one or more activities.

Collaborating organizations. (1) Contractors for the purchase of significant goods or services under the activity; or (2) organizations involved in the activity that do not receive any PCP3-source funds.

Contribution to results framework. The intermediate result expected from the activity, as specified in the USAID-mandated Results Framework for the PCP3.

Division. The Population Council is organized into several divisions. Program activities are carried out in three of these divisions, the Center for Biomedical Research (CBR), the International Programs Division (IPD), and the Policy Research Division (PRD). CBR conducts biomedical research, IPD conducts international programs, and PRD conducts policy research.

Implementing organization. The organization that receives USAID-source funds to undertake the activity—either the Council or a subrecipient.

Period. The expected period of the activity, beginning at the time Population Council Program funds were first spent on the activity (either under the current cooperative agreement or under an earlier cooperative agreement) and ending at the time it is expected no more PCP funds will be spent (either under the current cooperative agreement or under a subsequent cooperative agreement).

Population Council Product Development (PCPD). USAID Cooperative Agreement GPO-A-00-04-00019 with the Population Council (July 2004–June 2009). Selected product development work under the PCP3 received continued USAID funding under the PCPD.

Program. One of several bodies of work funded by the PCP3; divided into activities.

Technical coordinator. The Council staff member who oversees the activity.

Results framework. An outline provided by USAID to categorize the USAID strategic objectives to which work funded by the PCP3 will contribute, and to list the intermediate results leading to the strategic objectives.

Year One. 13 August 1999–31 August 2000, the first program year of the Population Council Program III cooperative agreement.

Year Two. 1 September 2000–31 August 2001, the second program year of the Population Council Program III cooperative agreement (overlaps with Year Three because of USAID-mandated change).

Year Three. 1 July 2001–30 June 2002, the third program year of the Population Council Program III cooperative agreement (overlaps with Year Two because of USAID-mandated change).

Year Four. 1 July 2002–30 June 2003, the fourth program year of the Population Council Program III cooperative agreement.

Year Five. 1 July 2003–30 June 2004, the fifth program year of the Population Council Program III cooperative agreement.

Year Six. 1 July 2004–31 August 2005, the sixth program year of the Population Council Program III cooperative agreement (consists of 14 months).

INTRODUCTION

The purpose of the Population Council Program III (PCP3) was to develop, evaluate, and bring to market new and better products for family planning and for prevention of sexually transmitted HIV/AIDS and other infections, as well as conduct demographic and social science research that was highly relevant to USAID programs and policy.

Contraceptive Development

The PCP3 supported work on a number of new contraceptive methods in the product pipeline. For women, these included a vaginal ring releasing the Council's synthetic progestin Nestorone® (NES) in combination with ethynylestradiol (EE); pharmacology and toxicology studies to complete the safety profile for all methods utilizing NES; a second-generation subdermal implant releasing NES; and a vaginal ring releasing a potent progesterone receptor modulator. The PCP3 also supported post-marketing activities on Norplant® and Jadelle® implants. For men, the PCP3 supported the development of a subdermal implant system releasing the synthetic androgen MENT; safety studies of MENT; and a novel antispermatogenic approach utilizing a product originally developed as an anti-cancer agent.

Microbicides Program

Under the PCP3, the Population Council continued research on microbicides. The PCP3 supported the development of the Population Council's lead microbicide Carraguard,® from funding technical assistance from Family Health International to the Council's Phase 2 expanded safety trial, to supporting a Phase 1 safety study among HIV-positive women and men, to major support for the mounting of a Phase 3 efficacy trial, all in South Africa. The PCP3 also supported development work on a contraceptive microbicide and on a second-generation non-contraceptive microbicide.

New Technologies and Strategies for RTI Interventions

A program of research to effectively diagnose and treat curable sexually transmitted infections, as well as improve efforts to prevent new infections, arose out of the work of the Microbicides Program, in the exploration of ways to facilitate and enhance microbicide clinical trials. Under the PCP3, the Council evaluated new technologies, including self-sampling techniques for STI sample collection and the use of rapid point-of-care diagnostics. Both new technologies were explored for home-based versus clinic-based use. Council researchers also documented partner notification strategies and prevalence of key infections as well as worked to improve reporting of sexual risk behaviors. This work generated useful information to improve public health systems and to reduce RTIs, as well as serving its original purpose in relation to HIV/STI prevention clinical trials. The process of implementing this program of work was effectively used to increase research capacity among local counterparts.

Expanding Contraceptive Choice

The Population Council's Expanding Contraceptive Choice (ECC) program worked to improve the reproductive health of women and men in developing countries by expanding their contraceptive choices and their options for preventing sexually transmitted infections (STIs), including HIV infection. The program aimed to increase the availability, accessibility, and use of safe, effective, and acceptable contraceptive and dual-protection technologies (methods that prevent both pregnancy

and STIs); and it sought to introduce (or reintroduce) these technologies in ways that were programmatically feasible and sustainable and were consistent with individuals' reproductive health goals. ECC staff worked with women's advocacy and health groups at community, regional, and national levels to increase individuals' informed choices within both health care and alternative service delivery systems. The program was guided by WHO's Strategic Approach to Contraceptive Introduction, a three-stage strategy designed to help policymakers and health professionals address the complex issues surrounding the introduction of contraceptive methods, including client preferences, service delivery system capabilities, provider competence, and sustainability.

Experimental Family Planning Studies in Rural Africa

An experimental study launched in northern Ghana by the Navrongo Health Research Center to assess the fertility and child-survival impact of alternative community health and family planning service strategies in rural traditional social settings was sustained for an additional six years under the PCP3. The study had already begun to demonstrate an impact on fertility decline in treatment areas, and under the PCP3 the full impact of the design and its operational components were observed. It was found that posting nurses to communities reduced childhood mortality rates by half, and adding community mobilization strategies and volunteer outreach to this approach led to a 15 percent reduction in fertility. When a replication project in the Volta Region demonstrated that the Navrongo service model could be transferred to a nonresearch setting, the Government of Ghana adopted the Navrongo approach as the health component of its national poverty-reduction strategy. In 1999, the Community-based Health Planning and Services (CHPS) initiative was launched to accelerate implementation of this policy. By mid-2005, CHPS was fully operational in 20 districts and under development in nearly every other district of Ghana. Analysis of successive phases of the Ghana program development process demonstrates feasible means of improving national access to reproductive and child health services.

Understanding and Meeting the Needs of Adolescents

The Population Council's program of research on transitions to adulthood in developing countries seeks to better understand adolescents' lives and to identify, design, and test various interventions to increase opportunities and reduce risks for adolescents, particularly girls. The ultimate goal is to allow adolescents to emerge as reproductively healthy adults with productive skills that will permit them to be full participants in work, family, and community life. The PCP3 partially supported research on adolescents in five countries: Three activities assessed the impact of new programs designed to affect the timing of marriage and childbearing and improve adolescent reproductive health, in order to identify policy interventions that will delay marriage and childbearing sufficiently to create the space in which more "successful" transitions to adulthood can occur, and at the same time contribute to filling that space with investments in improved capacities. The other two activities assessed a new technique designed to improve the accuracy of the data collected on adolescent sexual and reproductive behavior.

Transitions in Reproductive Behavior in the Developing World: Key Policy Issues

Over the past three decades, a revolution in reproductive behavior has swept through most of the developing world. Contraceptive use, once rare, is now widespread. The average number of births per woman has fallen by half—from six or more to nearly three. This program carried out four studies which shed light on several key issues related to the prospects for future trends in fertility and contraceptive use, including the future trend in the demand for contraception for the world and

its major geographic regions; the accuracy and significance of the "birth dearth" hypothesis; and the impact of family planning programs on differentials in contraceptive use and fertility within developing countries.

Urban Studies

The Nairobi Urban Health and Poverty Project (NUHPP) is a project of the Council-affiliated African Population and Health Research Centre intended to address the need for systematic research and experimental interventions focusing on problems of the urban poor. The PCP3 supported a needs assessment in 2002 in the four slum settlements in Nairobi, Kenya where the NUHPP project was slated. Later, the PCP3 supported research in Ouagadougou on urban malaria control.

Other Mission- or Core-Funded Initiatives

Several other activities which fit within USAID's results framework for the PCP3 were supported by the agreement. These activities were undertaken by Population Council researchers not on the staff of the other programs, and were therefore administratively separated into the groups "Mission-Funded Initiatives" and "Core-Funded Initiatives." Almost all of these activities took place in the field, with most funded by mission field support.

USAID RESULTS FRAMEWORK
for
POPULATION COUNCIL PROGRAM III

SO 1 To expand the range and optimize the use and availability of safe, effective and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.1 Improved and new contraceptive and reproductive health technologies developed, evaluated and approved.
- SR 1.1.a Improved biological knowledge base for understanding, prioritizing and applying new or existing technologies.
- SR 1.1.b Prototype technologies developed and tested.
- SR 1.1.c FDA and/or host country approval obtained.
- SR 1.1.d Private sector partnerships established.

IR 1.2 Use of contraceptive and reproductive health technologies optimized and expanded.
- SR 1.2.a Expanded knowledge of client acceptability, use dynamics, provider perspectives, and risks and benefits of technologies.
- SR 1.2.b Products, tools, technologies and knowledge transferred in a form that can be received, utilized and sustained; products introduced.
- SR 1.2.c Improved understanding of service delivery strengths and weaknesses as related to expanding technologies.
- SR 1.2.d Effective linkages created between reproductive health technologies and development of other health technologies.

IR 1.3 Microbicides and microbicides/spermicides developed, evaluated and approved.
- SR 1.3.a Improved biological knowledge abase for understanding, prioritizing, and applying new or existing technologies.
- SR 1.3.b New and improved methodologies, tools and technologies for management training, IEC, policy, data collection, and evaluation developed and tested.
- SR 1.3.c Prototype technologies developed and tested.
- SR 1.3.d FDA and/or host country approval obtained.

SO 2 Improved policy environment and increased global resources for family planning and reproductive health programs.

IR 2.1 Policy reform and program planning decisions at all levels are informed by timely and accurate data.
- SR 2.1.a National and operational policies relating to family planning and reproductive health formulated, disseminated, and implemented, and barriers to service availability removed.
- SR 2.1.b Inappropriate barriers to information and services for special populations are removed.

SO 3 Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

IR 3.1 New and improved strategies developed, tested and evaluated.

- SR 3.1.a Innovative service delivery strategies developed and evaluated and existing strategies improved.
- SR 3.1.b Policy reform and program planning decisions at all levels are informed by timely and accurate data.
- SR 3.1.c Enhanced understanding of issues contributing to change of reproductive intention and behavior.

Contraceptive Development

Program Summary

USAID provided major funding for the Contraceptive Development program under the Population Council Program III (PCP3) cooperative agreement. These funds supported work on a number of new methods in the product pipeline. For women, this included a vaginal ring releasing the synthetic progestin Nestorone® (NES) in combination with ethynylestradiol (EE); pharmacology and toxicology studies to complete the safety profile for all methods utilizing NES; a second-generation implant releasing NES; and a vaginal ring releasing a potent progesterone receptor modulator. They also supported post-marketing activities on Norplant® and Jadelle® implants. For men, the PCP3 supported the development of a subdermal implant system releasing the synthetic androgen MENT; safety studies of MENT; and a novel antispermatogenic approach utilizing a product originally developed as an anti-cancer agent.

Female methods

A Phase 2 study completed in Year Three (2002) investigated the effect of various doses of NES/EE rings when used on a bleeding signal regimen, where the ring was left in continuously until menstruation commenced, following which the ring was removed for four days and then reinserted whether bleeding had ceased or not. Following completion of the bleeding signal study, the decision was taken to develop a ring that releases NES/EE in a dose of 150/15 μg/day on a three-weeks-in, one-week-out usage schedule. Three studies were carried out to complete the safety profile of the NES/EE ring. A review of the data from the three studies took place at the April 2004 meeting of the International Committee on Contraception Research; the data confirmed that the NES/EE ring was safe for further development and entry into a pivotal Phase 3 trial for registration. Negotiations were undertaken with potential contract manufacturers for the NES/EE ring, since in order to register the ring with the FDA, a large-scale Phase 3 study must be carried out with rings made using the mass-manufacturing method. A contract manufacturer, QPharma of Malmö, Sweden, was identified to make the rings. Technology transfer, validation of the manufacturing process, and planning for the mass manufacture of the rings—a very difficult and time-consuming series of processes—were carried out. Further development of the NES/EE ring continues under the Population Council Product Development cooperative agreement.

Various preclinical pharmacology and toxicology studies of NES were undertaken. These studies indicated that NES is not carcinogenic, has neither mineralocorticoid nor anti-mineralocorticoid activity, does not cause local toxicity, and is non-genotoxic. They also indicate that use of NES does not lead to interactions with other drugs, and that NES is significantly more antiestrogenic than two other progestins evaluated as comparators.

An implant releasing NES was tested in a clinical trial. NES is not active orally as a result of a high rate of first-pass hepatic metabolism, a feature that makes the NES implant ideal for lactating women. Although initial results of this trial were favorable, three pregnancies occurred at months 18, 21, and 24 of implant use. Accordingly, the decision was made to close out the trial. Efforts to interest a partner in the commercialization of this approach for lactating women are ongoing.

The PCP3 supported preclinical work and a Phase 1 study of a vaginal ring releasing CDB-2914, a progesterone receptor modulator. Rings were manufactured and *in vitro* release rate studies indicated that the molecule was readily absorbed into the blood stream and ovulation was suppressed in some women. Data from the Phase 1 study suggested that a significant increase in the dose delivered per day would result

in a continuous, bleed-free method of contraception. Subsequent studies of the approach were funded from sources other than USAID.

In an effort to expand the cost effectiveness of the Norplant implant, Council staff focused on extending the use-life of this implant system from five to seven years of contraceptive effectiveness. Data was analyzed and submitted to the U.S. Food and Drug Administration (FDA), which deemed the submission "approvable," while at the same time requesting additional information from the Council and the manufacturer. The Council's effort to extend the use-life to seven years continues with funding under the Population Council Product Development cooperative agreement.

A similar effort was mounted in support of Jadelle. Clinical trials of this highly effective implant system, completed during 1999, strongly supported a claim of effectiveness beyond the approved three years of use. The data from these studies were collected, processed, assembled, and submitted to the FDA in September 2000; Jadelle was approved for five years of use in women on November 22, 2002, significantly enhancing the cost effectiveness of this method.

Male methods

For men, the Council's lead product was an implant releasing the synthetic androgen MENT. A multicenter dose-finding study was concluded, with subjects responding in a dose-dependent fashion. To enhance the antispermatogenic response, implants were reformulated and a study was carried out to compare MENT alone with three groups of various MENT-plus-levonorgestrel dose combinations. Subjects in all groups at each of the three participating clinics showed suppression of testosterone. Sperm suppression was uneven, however, and there were wide inter-clinic variations. As the trial was designed to be truncated at six months of use if less than 70% of subjects achieved azoospermia (the absence of sperm in semen), the decision was taken to close out the study. A series of toxicology and pharmacology studies of MENT were carried out to establish the safety profile of MENT. These indicated that MENT is neither toxic nor genotoxic, and that MENT supports bone and muscle growth without overstimulating the prostate.

Analogs of lonidamine, a drug originally developed to treat cancer, were found to have potent antispermatogenic effects *in vivo*. A series of toxicity and genotoxicity studies of AF-2364, one of the lonidamine analogs, showed no chromosomal damage or other toxic effects in animals treated with the compound at the doses tested. Preliminary pharmacokinetic studies were also conducted to investigate the clearance of AF-2364. Findings indicated that the drug was detectable within one hour of oral administration, and was then rapidly cleared from the systemic circulation. It was virtually undetectable within 24–48 hours, indicating that it is rapidly absorbed through the gastrointestinal tract. AF-2364 was not detected in the cerebrospinal fluid or brain extracts of rats treated with the molecule, suggesting that the compound does not cross the blood-brain barrier.

Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring

Project Number/s: **07902**
Country/ies: Australia, Chile, Dominican Republic, Finland, France, Netherlands, United States
Technical Coord.: Regine Sitruk-Ware, Bruce Variano
Period: Pre-Year One – June 2009
Objective: To develop a new contraceptive ring system that is under the control of the user and does not require daily oral intake of steroids, thus avoiding the impact of oral steroids on the liver and reducing side effects related to androgenic progestins.

Activity Description:

The contraceptive ring is particularly suitable for steroid administration. When a ring is placed in the vagina, the steroid within it slowly diffuses into the blood and tissues, thereby providing a contraceptive effect by inhibiting ovulation. Because the ring is inserted and removed by the woman herself, a minimal amount of attention by medical personnel is required, and initiation and discontinuation of ring use are under the woman's control. The contraceptive vaginal ring containing NES and EE is undergoing extensive clinical trials to facilitate its approval by regulatory agencies and, eventually, introduction into family planning programs.

The ring is designed for one year of use. The results of dose-finding and use-schedule studies showed the release of NES/EE at a rate of 150/15 μg per day to be the most effective dose. As to the use schedules, both the three-weeks-in/one-week-out and the 26-days-in/4-days-out schedules showed excellent bleeding control and were equally effective in the prevention of pregnancy.

Commercial relationship: QPharma, ring manufacture

Final Report:

Prior to the commencement of the PCP3 Cooperative Agreement, a series of Phase 2 trials was conducted to determine the appropriate NES/EE dose and to evaluate use regimens for the NES/EE ring. In the first half of 2002, under the PCP3, an additional Phase 2 study was completed to investigate the effects of various doses of ring-delivered NES/EE when used on a bleeding signal regimen; in this study, the ring was left in continuously until menstruation commenced, the ring was then removed for four days, and the ring was then reinserted whether or not bleeding had ceased. Following completion of this bleeding signal study, the decision was taken to develop a ring that released NES/EE in a dose of 150/15 μg per day (which had been found to be the most effective dose combination), on a three-weeks-in/one-week-out usage schedule (there had been no pregnancies among the women using this schedule in the studies completed prior to the PCP3).

Three studies were carried out in 2003 and 2004 to complete the safety profile of the NES/EE ring. First, a study of hepatic factors among women using the ring compared with women using an oral contraceptive (OC) was conducted by investigators with extensive experience in studying the effects of drugs on liver proteins, at a clinical site in Leiden, the Netherlands. Second, a study comparing vaginally-delivered EE and orally-delivered EE was carried out by the International Committee for Contraception Research (ICCR) investigator in Paris to determine whether ring delivery of EE is equivalent to oral intake of the compound in the stimulation of liver proteins. Third, a pharmacokinetics study of the NES/EE ring in comparison with a well-accepted OC was conducted at the ICCR clinic in Los Angeles. Characteristic of sustained-release

contraceptive methods with a deeply buried drug reservoir, the rings release a burst of EE immediately upon insertion; this study was designed to compare the EE serum levels reached as a result of this burst with the levels of EE reached daily among users of the OC.

A review of the data available from the above three studies took place at the April 2004 ICCR meeting. The data had confirmed that the effect of EE on liver proteins is similar whether the steroid is administered orally or vaginally, and showed that some of the metabolic effects of the vaginal ring are similar to what is observed with third-generation OCs. Therefore, although the objective of developing a contraceptive ring system which avoids the impact of steroids on the liver was not achieved, it was determined that the effective dose of administered steroid can be lower with a ring than with OCs, thus partially avoiding side effects related to androgenic progestins on lipids. As a result of these data and findings, the NES/EE ring was determined to be safe for further development.

In 2003, negotiations were undertaken with potential contract manufacturers for the NES/EE ring, since, in order to register a product with the FDA, a large-scale Phase 3 study must be carried out with rings made using a mass-manufacturing method. A contract manufacturer, QPharma of Malmö, Sweden, was identified to make the rings. Technology transfer, validation of the manufacturing process, and planning for the mass manufacture of the rings, a very difficult and time-consuming series of processes, has been completed under the Population Council Product Development Cooperative Agreement.

Implementing Organization(s): Sydney Center for Reproductive Health Research (CB99.025A)
Health Research Associates, LAC/USC (CB99.020A)
The Family Federation of Finland (CB99.001A)
Saint-Antoine Hospital, Paris (CB03.107A)
Health Research Associates, LAC/USC (CB03.106A)
Netherlands Organization for Applied Scientific Research (CB02.111A)

Collaborating Organization(s): Chilean Institute of Reproductive Medicine (ICMER)
Dominican Association for the Well-Being of the Family (PROFAMILIA)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Nestorone® (NES) Implant

Project Number/s: **07703**
Country/ies: United States
Technical Coord.: Irving Sivin
Period: Pre-Year One – December 2003
Objective: To develop a single implant releasing NES that will provide contraceptive protection while avoiding the adverse effects of oral steroids on the liver and reducing side effects related to androgenic progestins.

Activity Description:

A single implant releasing the progestin NES and intended for two years of use is being developed by the Population Council. The steroid is not active orally as a result of a high rate of first-pass hepatic metabolism, a feature that makes the NES implant an ideal method for lactating women. A Phase 2 dose-finding study indicated that a dose corresponding to an *in vitro* release rate of 100 µg per day exhibited good suppression of ovulation and prevented pregnancy through 23 months. A single pregnancy occurred in the 24th month. Accordingly, the implant was redesigned to provide an *in vitro* release rate of approximately 115 µg per day. The reformulated implant was 4.5 cm long, had a smaller diameter, and contained a higher drug load. These features were expected to extend the implant's effectiveness to two full years and, with respect to pregnancy prevention, provide a margin of safety of a few months beyond two years. A Phase 2b clinical trial of the reformulated implant was initiated during Year One of the Population Council Program III. Although initial results of this trial were favorable, one pregnancy occurred during each of the first three months of 2002. The pregnancies occurred at months 18, 21, and 24 of implant use. Accordingly, the decision was made to close out the trial in the period late Year Three/early Year Four.

Final Report:

USAID funds under the PCP3 supported in-house activities associated with Protocol 263, the Phase 2b clinical study of the reformulated NES implant (described under the Activity Description). These activities included pre-clinical studies such as implant manufacturing, *in vitro* studies of implant release rates, and costs associated with clinical monitoring activities. Also included were activities involving regulatory affairs paperwork related to closing out the study, and the preparation of a manuscript for publication of the study results.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Nestorone® (NES), Not Method-Specific

Project Number/s: **07600**
Country/ies: United States
Technical Coord.: Narender Kumar
Period: Pre-Year One - Post-Agreement
Objective: To conduct synthesis and formulation of NES; radioimmunoassay of clinical blood samples; and pharmacology, metabolism, and toxicology studies required by regulatory agencies for all methods using NES.

Activity Description:

In order to carry forward the clinical studies of NES, various safety, pharmacology, and metabolism studies are required. Studies seek to generate a body of data that will meet the regulatory requirements for clinical trials of all methods releasing NES.

Commercial relationship: Crystal Pharma, NES synthesis

Final Report:

The following preclinical pharmacology and toxicology studies, required by the FDA in order to complete the safety profile of NES for approval and registration of the NES/EE contraceptive vaginal ring, were undertaken and completed during the PCP3 Cooperative Agreement:

· A two-year, placebo-controlled carcinogenicity study was carried out in rats, using three dose levels of NES, administered via subdermal implants. NES was found to be non-carcinogenic.

· A dose-finding study was undertaken in preparation for a six-month carcinogenicity study in transgenic mice. The carcinogenicity study in transgenic mice that followed indicated no carcinogenic activity of NES.

· An enzyme induction study in cultured human hepatocytes to investigate the potential for NES to induce cytochrome P450 isoenzymes was completed. Cytochrome P450 isoenzymes are important for oxidative metabolism in the liver. Changes in drug metabolism can lead to drug interactions, which may result in toxicity, treatment failure, or loss of drug effect. The study showed that NES did not induce cytochrome P450 isoenzymes. Thus, it is unlikely that NES use will lead to any drug interactions.

· The mineralocorticoid/anti-mineralocorticoid activity of NES was investigated in bilaterally adrenalectomized rats. The results showed that NES alone (in 2 and 20 μg injections) had no mineralocorticoid-like activity in this assay. Also, NES did not inhibit the mineralocorticoid activity of aldosterone, leading to the conclusion that NES has neither mineralocorticoid nor anti-mineralocorticoid activity at the dose levels tested.

· A local toxicity study of rings releasing NES in cynomolgus monkeys was completed; no local toxicity occurred.

· The anti-estrogenic effects of NES were studied in ovariectomized rats. Results indicated that NES is significantly more antiestrogenic than ketodesogestrel and levonorgestrel, the other two progestins evaluated (ketodesogestrel and levonorgestrel are both approved and in use in oral contraceptive formulations worldwide).

· A genotoxicity study of NES was completed. NES was found to be nongenotoxic in a mammalian erythrocyte micronucleus test, in a bacterial reverse mutation assay, and in an *in vitro* mammalian chromosome aberration test.

· The metabolism of NES using rat and human liver tissue was investigated; no adverse effects of NES were observed.

· In addition to the pharmacology and toxicology studies described above, radioimmunoassay was carried out on clinical blood samples from all NES/EE vaginal ring and NES implant clinical trials in order to ensure that the blood levels of NES were sufficient to inhibit ovulation.

Work on this project is ongoing under the Population Council Product Development Cooperative Agreement: a study of the absorption, distribution, metabolism, and excretion (ADME) of NES in rats is taking place (a prerequisite to a study of the excretion and metabolism of NES in women), and a 26-week carcinogenicity study of NES in mice is planned. Submission of the NES safety data to the FDA will occur following completion of the NES/EE Ring Phase 3 clinical trial.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Androgen Implant

Project Number/s: **07801**
Country/ies: Chile, Germany, United States
Technical Coord.: Narender Kumar
Period: Pre-Year One – June 2004
Objective: To develop an implant releasing the synthetic androgen MENT™ to suppress spermatogenesis and replace testosterone in normal, fertile men.

Activity Description:

Suppressing spermatogenesis by blocking gonadotropin secretion is a promising approach to male contraception. MENT, a synthetic androgen, is a potent suppressor of gonadotropin secretion, which leads to a reduction of testosterone production and cessation of spermatogenesis. Prior to implant fabrication, MENT is converted to MENT acetate (MENT Ac), as the acetate form of the drug is more readily released from subdermal implants. MENT Ac is rapidly hydrolyzed into MENT *in vivo*. Because of its high potency, the effective doses are very low, making it feasible for MENT to be administered for extended periods via implants. MENT Ac implants have been developed and tested in normal and hypogonadal men and found to elicit dose-related responses.

Final Report:

During the PCP3, a multicenter dose-finding study of MENT Ac implants was concluded (Protocol 246). A total of 36 normal men were enrolled at three ICCR clinics and used one, two or four MENT Ac implants. Suppression to azoospermia occurred in nine of 11 subjects in the four-implant group compared to two of 11 subjects in the two-implant group and none of 12 subjects in the single-implant group. During treatment no serious general side effects, signs of androgen deficiency, or extrusion of implants were observed.

Efforts were undertaken subsequent to the study to reformulate the implants so that fewer implants would be required to deliver sufficient MENT to provide a contraceptive effect. In addition, as several reports from other laboratories indicated that a combination of a synthetic progestin such as levonorgestrel and an androgen may be an effective approach for male contraception, a study was planned to compare MENT alone, released from reformulated implants, with three groups of various MENT-plus-levonorgestrel dose combinations (Protocol 320). The three clinical sites were Münster, Germany, Santiago, Chile, and Los Angeles. Subjects in all groups at each of the three clinics showed suppression of testosterone. Sperm suppression was uneven, however, and there were wide inter-clinic variations. In general, subjects in the Los Angeles clinic responded best to treatment and subjects in Münster responded the least. These responses appear unrelated to the ethnicity of the study subjects. As the trial was designed to be truncated at 6 months of use if more than 30% of subjects did not achieve azoospermia (the absence of sperm in semen), the decision was taken to close out the study. Implant removal proved to be a challenge in some subjects, as the reformulated MENT implants were made with thinner tubing, in order to allow for greater drug content. For this reason, future studies of the MENT implant will utilize the original formulation of implants.

USAID support was also used during PCP3 to support the in-house costs for an investigator-initiated study by the Medical Research Council in Edinburgh, Scotland (Protocol 349). The study compares the original formulation of MENT implants in combination with Implanon® (a single, progestin-releasing implant that

is on the market for female contraception), and testosterone pellets, also in combination with Implanon. A total of 36 subjects are taking part, with 18 randomized to each treatment arm.

Implementing Organization(s): Institute of Reproductive Medicine of the University of Münster (CB99.016A)
Harbor-UCLA Research & Education Institute (CB02.108A)
Institute of Reproductive Medicine of the University of Münster (CB02.107A)
Chilean Institute of Reproductive Medicine (ICMER) (CB02.106A)
Population Council

Collaborating Organization(s): Dominican Association for the Well-Being of the Family (PROFAMILIA)
UK Medical Research Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Androgen, Not Method-Specific

Project Number/s: **12400**
Country/ies: United States
Technical Coord.: Narender Kumar
Period: Pre-Year One – June 2004
Objective: To conduct synthesis and formulation of MENT™; radioimmunoassay of clinical blood samples; and pharmacology, metabolism, and toxicology studies required by regulatory agencies for all methods using MENT.

Activity Description:

In order to carry forward the clinical studies of MENT, various safety, pharmacology, and metabolism studies are required. Studies seek to generate a body of data that will meet the regulatory requirements for clinical trials of all methods releasing MENT.

Commercial relationship: Schering AG, development

Final Report:

Various toxicology, mutagenicity, and absorption, distribution, metabolism, and excretion (ADME) studies of MENT were carried out during PCP3 to establish the safety profile of this molecule. A chronic toxicology study was completed in rats and monkeys, indicating that MENT is not toxic and is safe for further development. Mutagenicity studies were completed per U.S. Food and Drug Administration guidelines. These showed no evidence of genotoxic potential on the part of MENT. *In vitro* studies to identify the liver enzymes involved in the metabolism of MENT Ac were completed. It was determined that both rat and human liver metabolize MENT Ac in a similar way. The effects of androgens on protein synthesis and degradation machinery was investigated. Results showed that androgens have an effect on the proteosome pathway in muscle, suggesting a possible mechanism for the anabolic action of androgens.

A study was carried out to evaluate the bone- and muscle-sparing potential of MENT. The study was conducted in an aged orchiectomized rat model. Rats were treated with 4, 12, or 36 µg/day of MENT via mini-osmotic pumps. Prostate weights were increased above normal only in the high dose group. In contrast, all three MENT doses were equally bone sparing at the spine, hip and tibia. This suggests that low doses of MENT would support bone and muscle growth without overstimulating the prostate. Additional studies were planned to investigate if aromatization of MENT to estradiol is required for bone-sparing effects of MENT.

Also included under this category is radioimmunoassay of serum samples for MENT from the clinical trials of MENT Ac implants (Protocol 246) and MENT Ac implants in combination with progestin implants (Protocols 320 and 339).

Implementing Organization(s): Population Council

Collaborating Organization(s): University of Helsinki

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

CDB-2914 (Progesterone Receptor Modulator)

Project Number/s: **07909**
Country/ies: Chile, Dominican Republic, United States
Technical Coord.: Yun-Yen Tsong
Period: July 2001 – June 2003
Objective: To evaluate the effectiveness of a vaginal ring delivering CDB-2914 on a continuous basis.

Activity Description:

Data from studies conducted in Population Council laboratories indicate that the potent progesterone receptor modulator CDB-2914 can cross the vaginal mucosa in rabbits. *In vitro* tests of the molecule in a ring formulation indicate that it diffuses through the silastic of the ring. A ring is envisioned that women can use on a continuous basis.

Final Report:

USAID support under PCP3 for the vaginal ring delivering CDB-2914 included pre-clinical work (including ring manufacture and *in vitro* release studies) in support of the initial clinical trial to test this ring (Protocol 312). Protocol 312 was carried out during Year Four of the Population Council Program III to evaluate a ring releasing approximately 400 µg of the progesterone receptor modulator CDB-2914. The objectives were to determine the absorption of the molecule, the effect of CDB-2914 on ovulation, and its effect on the endometrium. Pharmacokinetic data indicate that CDB-2914 was readily absorbed into the bloodstream, reaching a plateau at serum levels of 2–3 ng/mL, as measured by radioimmunoassay. Ovulation was completely suppressed in three women, delayed in four, and was normal in five. Endometrial biopsies were taken on day 28 of ring use for all 12 subjects. Most of the subjects were in the secretory phase with endometrial maturation markedly delayed in all subjects. With the exception of two subjects, no bleeding occurred during ring use. Withdrawal bleeding occurred following a decrease in progesterone levels. These results indicate that the dose of CDB-2914 tested in this study was partially effective in preventing or delaying ovulation in a few subjects. The changes observed in the endometrium also indicate a local effect of the progesterone receptor modulator. The data suggest that an increase of 25–50 percent of the dose delivered per day will result in ovulation suppression.

Implementing Organization(s): Chilean Institute of Reproductive Medicine (ICMER) (CB02.103A)
Dominican Association for the Well-Being of the Family (PROFAMILIA) (CB02.102A)
Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Lonidamine Analogs

Project Number/s: **08510**
Country/ies: United States
Technical Coord.: C. Yan Cheng
Period: July 2001 – June 2002
Objective: To evaluate the male contraceptive potential of two analogs of lonidamine.

Final Report:

Data from Population Council laboratory studies indicate that two analogs of lonidamine (1-halobenzyl-1H-indazole-3-carboxylic acid) have potent antispermatogenic effects *in vivo*. Preliminary animal studies have shown both compounds to be potential candidates for male contraceptives.

In Year Three of the Population Council Program III, two genotoxicity tests were initiated: (1) a mammalian erythrocyte micronucleus test assessing the ability of the lonidamine analog AF-2364 to induce micronucleated polychromatic erythrocytes in mouse bone marrow; and (2) an *in vitro* mammalian chromosome aberration test evaluating the clastogenic potential of AF-2364 to induce chromosome aberrations in Chinese hamster ovary cells. Both tests were designed to determine whether AF-2364 can induce chromosomal damage in cells exposed to this compound at various dose levels. An acute oral toxicity test (single dose) was also initiated in rats. These studies were conducted by licensed toxicologists. Results became available in the third quarter of 2002. A micro-analytical assay methodology was developed for AF-2364 using HPLC. Preliminary pharmacokinetics studies were conducted to investigate the clearance of AF-2364. Following a single administration of AF-2364 (either [3H]-AF-2364 or unlabeled AF-2364) by gavage, AF-2364 was detected in serum within one hour, peaked at 3–6 hours, and rapidly cleared from systemic circulation. Within 24–48 hours, AF-2364 in serum was virtually undetectable, suggesting that AF-2364 is rapidly absorbed through the gastrointestinal tract. A similar pattern was obtained by quantifying AF-2364 in urine samples of treated adult rats. AF-2364 was not detected in cerebrospinal fluid or in brain extracts, suggesting that the compound did not traverse the blood–brain barrier. AF-2364 uptake by the testis is rapid.

USAID did not continue to fund this activity after Year Three.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Norplant®

Project Number/s: **07701**
Country/ies: United States
Technical Coord.: Irving Sivin
Period: Pre-Year One – June 2003
Objective: To secure from the U.S. Food and Drug Administration (FDA) approval of Norplant as a seven-year method.

Activity Description:

Norplant is a set of six 3-cm implants that release the progestin levonorgestrel at declining rates over a ten-year period. The implants are currently approved by regulatory agencies for five years of use. However, clinical data suggest that the release rates of the progestin are sufficient to provide a high degree of effectiveness in preventing pregnancy for a period of seven years. The data show the cumulative five-year pregnancy rate to be 1.1 per 100, and the seven-year cumulative pregnancy rate to be 1.9 per 100. Annual pregnancy rates have always been below 1 per 100 throughout the seven-year clinical trial. The Population Council expects that Norplant will eventually be replaced by another Council product, Jadelle®, which also releases levonorgestrel; however, the registration of new products in a large number of countries takes place over many years (it took 17 years to register Norplant in 63 countries). Accordingly, the Council sought to extend the period of regulatory approval for Norplant from five to seven years, addressing the request to the FDA.

Final Report:

In an effort to secure a label change of Norplant from five to seven years of contraceptive effectiveness, work has focused on determining *ex vivo* residual drug in implants from clinical trials that began in 1990, and relating duration of use to *ex vivo* release rates, both for women who became pregnant and for those who did not. Data analysis was completed during Year Four, and all of the data required for a submission of extension of use life to seven years was submitted to the FDA. The FDA sent a letter to the Council noting that the submission was "approvable," but with additional questions. The questions that the Council (as opposed to Schering-Leiras, the manufacturer) is required to answer will be submitted to the FDA early in Year Five. The Council has not yet reached agreement with the manufacturer as to their willingness to provide the FDA with responses to questions that are in its area of expertise. However, Schering-Leiras has indicated that it is no longer resistant to a seven-year label change. Funding for this activity ended during Year Four of the Population Council Program III; any future work on this activity will be carried out using non-USAID funds.

Implementing Organization(s): Population Council
Collaborating Organization(s): National University of Singapore
Siriraj Family Health Research Center

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Jadelle® (Two-Rod Levonorgestrel Implant System)

Project Number/s: **07702**
Country/ies: United States
Technical Coord.: Fred Schmidt, Irving Sivin
Period: Pre-Year One – Post-Agreement
Objective: To secure from the U.S. Food and Drug Administration (FDA) approval of Jadelle as a five-year contraceptive method.

Activity Description:

Jadelle (formerly known as Norplant® II) is a set of two 4-cm implants that release the progestin levonorgestrel steadily over five years and at reduced rates for two to three years thereafter. The Population Council, with the support of USAID, received FDA approval in 1996 for use of this contraceptive for three years. Clinical trials have continued, and the five-year cumulative pregnancy rate is 1.1 per 100 women, with an average annual Pearl pregnancy rate of less than 0.2 per 100 woman years. Because the longer use-life is believed to be advantageous to women seeking long-term protection against pregnancy, the Council wishes to obtain FDA approval for five years of use.

Commercial relationship: Schering Oy, manufacturing and marketing

Final Report:

Clinical trials of Jadelle were completed in 1999. Data from the trials had strongly supported a claim of effectiveness for five years, as the five-year cumulative pregnancy rate was 1.1 per 100 women and the efficacy of the rod implants for five years matched that of the highly effective "soft tubing" Norplant® capsule system. Efforts to collect, process, and assemble data on Jadelle to support extending use-life beyond three years commenced in 1999. Analysis of data collected in these studies was filed with the Finnish Regulatory Agency in July 2000, which provided the basis for the Agency's extension of the approved use-life from three to five years. In September 2000, a regulatory submission was made to the FDA requesting approval for a five-year use-life of Jadelle, which was granted on November 22, 2002. This extension of use-life will significantly enhance the cost-effectiveness of this method and will better enable public sector agencies such as USAID to provide this highly-effective systemic method to low-income women in less-developed countries.

In each year of the PCP3 Cooperative Agreement, Council staff prepared postmarketing reports to submit to the FDA in order to maintain the Council's New Drug Application (NDA) for Jadelle. The reports included: the annual report, with a summary of any significant new information from the previous year that might affect the safety, effectiveness, or labeling of the product; distribution data; a summary of labeling changes; a description of manufacturing changes not requiring a supplemental application; summaries of unpublished and published nonclinical and clinical studies for the previous year; and status reports of postmarketing study commitments.

Additionally, staff submitted NDA supplemental applications for chemistry and manufacturing information provided by the manufacturer that required a change in the manufacturing and control methods and procedures.

Work on this activity, including the submission of NDA supplemental applications to the FDA, is continuing under the Population Council product Development Cooperative Agreement.

Implementing Organization(s): Population Council
Collaborating Organization(s): National University of Singapore
Siriraj Family Health Research Center
Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Microbicides Program

Program Summary

With significant support from the US Agency for International Development (USAID), the Population Council has been at the forefront of an international movement to develop vaginal microbicides—female-initiated products that would kill, inactivate, or block HIV and other sexually transmitted infections. The Population Council's Microbicide Product Research and Development Program is a collaborative effort of two of the Council's research divisions: the Center for Biomedical Research and the International Programs Division. For over 15 years, the Microbicides Program has included a broad spectrum of activities necessary for developing, testing, and producing microbicides, including basic research, product development, clinical trials, behavioral studies, and public education.

Under the Population Council Program III (PCP3), USAID provided $300,000 over the first two years to support ongoing technical assistance from Family Health International to the Phase 2 expanded safety trial in South Africa of Carraguard®, the Population Council's lead microbicide, as well as seed money to begin a Phase 1 safety study of Carraguard among HIV-positive women in South Africa. The dramatic increase in funding to over $3 million a year in Years Three and Four and almost $7 million in Year Five of the agreement allowed a significant expansion of the Microbicides Program, enabling completion of the Phase 1 safety study among HIV-positive individuals, mounting of a Phase 3 efficacy trial of Carraguard, and development work on a contraceptive microbicide and on a second-generation non-contraceptive microbicide.

Phase 3 Efficacy Trial of Carraguard

The greatest achievement was beginning the Phase 3 efficacy trial of Carraguard, currently ongoing at three sites in South Africa: Gugulethu, implemented by the University of Cape Town; Soshanguve, implemented by the University of Limpopo/Medunsa Campus; and Isipingo, implemented by the South African Medical Research Council (MRC). As this trial is one of the first microbicide Phase 3 efficacy trials of a novel product, its initiation in March 2004 was a major event, with several important milestones along the way.

PCP3 funding enabled the creation of two research centers, the Empilsweni Centre for Wellness Studies in Gugulethu and the Setshaba Research Centre in Soshanguve. These two state-of-the-art clinics are enrolling more than 4,000 women (over 2,000 per site), a ten-fold increase over Phase 2 capacity. The PCP3 also supported the first six months of the scale-up process at the MRC site in Isipingo. In addition to increasing physical capacity with substantial renovations, Phase 3 preparation and scale-up at the study sites included hiring staff (approximately 35 people at each site) and training them in Good Clinical Practice (GCP), developing on-site laboratories, producing a recruitment video and study booklet to educate potential study participants, and establishing relationships with the local communities. As of August 31, 2005, 4,361 women had been enrolled in the trial, surpassing the expected enrollment rate of 50%.

Another major achievement was completing the procedural scale-up for gel manufacturing for the Phase 3 trial at Clean Chemical Sweden (CCS), including all required documentation for the Chemistry, Manufacturing, and Control (CMC) file, required by regulatory authorities. The successful scale-up at CCS has enabled continuous gel production to keep pace with study needs. Headway was also made in documenting Carraguard's stability, another important aspect of the regulatory file, particularly to enable

registration of Carraguard as an over-the-counter product. Under the PCP3, it was determined that Carraguard is stable for at least two years. (Stability testing to establish a five-year stability profile continues under the follow-on Population Council Product Development cooperative agreement [PCPD].)

The management of the Phase 3 trial also features several important accomplishments. The Council is the first microbicides trial sponsor to develop a biological marker to test for applicator usage. This test can determine if applicators were actually inserted in the vagina, information that will enable a much better sense of adherence than that gained from interviews only. This technology has been applauded by the U.S. Food and Drug Administration, and other sponsors have approached the Council about using the applicator test in their future trials. In addition, a bar code system was introduced to track used and unused applicators. The bar code system has been extremely helpful for product management, both in terms of product accountability as well as to determine if gel has been shared between participants. The Council also instituted the DataFax system for data management. This system allows us to keep data entry up-to-date, and functions reliably in places such as South Africa where access to the Internet is unreliable. In addition to being a valuable tool for the Carraguard Phase 3 trial, DataFax has increased capacity at the Council for other clinical trials.

In addition to the main trial outcome — determining if Carraguard reduces risk of HIV transmission in women — special aspects of the trial are also being studied. An evaluation of the informed consent process began in Gugulethu and Soshanguve, to assess whether the video has an impact on comprehension and willingness to participate. The evaluation will be completed under the PCPD agreement. Also in Soshanguve, a study co-funded by the PCP3 and the Hewlett and MacArthur Foundations began, which aims to explore the referral network for HIV-positive women to determine if women identified as HIV-positive at screening are using the services and, if so, whether or not the services meet their needs.

The Phase 3 efficacy trial of Carraguard will continue through 2007, supported by USAID under the PCPD and by the Bill & Melinda Gates Foundation. The wealth of data from this trial will be important for future microbicide trials at the Council, and for the microbicides field as a whole.

Phase 1 Safety Study among HIV-positive Women and Men in Durban

A second achievement on the clinical front was completion of a randomized, controlled, partially-blinded Phase 1 safety trial of Carraguard among HIV-positive men and women, implemented by the MRC in collaboration with the US Centers for Disease Control and Prevention (CDC). Ensuring the safety of a candidate microbicide among HIV-positive individuals is critical, as many men and women may not know their HIV status before using such a product. Carraguard was shown to be safe among this population, when compared with the placebo methyl cellulose or a no gel control arm. In addition to the primary outcome measures of safety (signs and symptoms of local irritation), Council researchers are also analyzing data from cervical-vaginal lavage samples to determine whether Carraguard has any impact on genital shedding of HIV, as well as data from the use of two novel techniques developed by Clyde Hart's laboratory at the CDC which will allow investigation of infectious virus within the lavage. These data will have broader implications than for microbicide studies alone, as scientists try to better understand genital shedding of HIV and how to measure it effectively. In addition to showing that Carraguard is safe, the study marked the first collaboration for a clinical trial between the Population Council and the MRC, paving the way for the MRC's participation in the Phase 3 efficacy trial.

PC-815: A second-generation microbicide

Second-generation microbicide products are hoped to be even more effective than Carraguard. In laboratory testing, PC-815 — a combination of Carraguard and MIV-150, an anti-retroviral —demonstrated effectiveness against a range of sub-types of HIV-1, and activity against HIV-1 and HIV-2 both in the presence and in the absence of seminal fluid. Development of PC-815 continues under the PCPD agreement.

CARRA/NES : A contraceptive microbicide

Though some women may need a non-contraceptive microbicide, a product is also needed that provides dual protection for both disease and pregnancy. CARRA/NES combines Carraguard with the hormonal contraceptive Nestorone, and it is being developed for use as an "on-demand dual protection" method. One of the greatest challenges has been developing a formulation that ensures optimal release and diffusion of Nestorone within the Carraguard gel formulation. Under the PCP3, considerable progress in pre-clinical work was made, including demonstration of even release drug kinetic profiles in *in vitro* and *in vivo* studies, and establishment of a six-month stability profile.

Basic research on HIV-transmission: Dendritic cells

During Year Five, the PCP3 agreement supported scientist Melissa Pope's studies on the function of dendritic cells in HIV transmission, as well as research to document the capacity of carrageenan and zinc-carrageenan to block virus captured by dendritic cells. *In vitro* studies showed that these formulations had no overt impact on dendritic cell biology, as well as preliminary evidence that they could limit dendritic cell to T-cell spread of HIV infection.

USAID's support of the Council's Microbicides Program has enabled accomplishment of a range of groundbreaking activities in basic research, product development, and clinical trials. In addition to directly supporting our work, funding from USAID led to successful fundraising from other donors, including the Bill & Melinda Gates Foundation and the Swedish International Development Cooperation Agency. We look forward to a continued collaboration with USAID through the PCPD agreement, and to continue to move the microbicide product development field forward.

IPD: Phase 1 Safety Study of Carraguard® (PC-515) Among HIV-Positive Women and Men

Project Number/s: **05603**
Country/ies: South Africa
Technical Coord.: Heidi Jones, Taja Ferguson, Barbara Friedland
Period: January 2000 – August 2005
Objective: To examine the safety and acceptability of Carraguard when used by HIV-positive women and men.

Activity Description:

This study will examine the safety and acceptability of Carraguard when used by HIV-positive women and men in Durban, South Africa. Researchers will examine genital shedding in women through analysis of cervical-vaginal lavage samples, and this will be the first study in which men are asked to apply Carraguard gel directly to the penis. The protocol includes three cohorts: 20 sexually abstinent women, 20 sexually abstinent men, and 20 sexually active women. Each cohort will be divided into three study arms: Carraguard, placebo gel, and no study product. Researchers will investigate the safety of Carraguard for use in this population by assessing changes in the vulvar, vaginal, and cervical epithelia, the vaginal flora, and HIV-1 shedding in the genital tract of female participants; changes of the penile skin and epithelia of male participants; and self-reported symptoms. A secondary objective of the study is to assess the acceptability of Carraguard and placebo gels. The study is being conducted in South Africa for several reasons. First, the high prevalence of HIV in South Africa allows for easy recruitment of adequate numbers of HIV-positive participants. Second, many potential users of microbicides in South Africa are likely to be HIV-positive without knowing their HIV status. Last, it is likely that South Africa would be one of the first places microbicides would be launched once approved. IPD staff are collaborating with Gita Ramjee of the Medical Research Council (MRC) in KwaZulu-Natal, which has an extensive research infrastructure.

Final Report:

We completed a randomized, placebo-controlled trial to assess the safety of Carraguard among HIV-positive women and men in Durban, South Africa. The study results, described below, showed that Carraguard is both safe and acceptable for topical use among HIV-positive women and men.

The study took longer than anticipated due to implementation challenges. The original protocol included three cohorts: 15 abstinent HIV-positive women, 15 abstinent HIV-positive men and 50 sexually-active HIV-positive concordant couples. However, the protocol was amended five times between July 2001 and January 2003 to facilitate recruitment and enrollment. Major protocol changes were: enrolling 20 sexually active women instead of 50 sexually active couples, based on concerns about the feasibility of male partner participation; increasing the sample size to account for a change in handling non-adherent participants or those lost to follow-up (we decided to over-enroll participants instead of replacing participants who were non-compliant, withdrew early from the study, or were lost to follow-up); and to clarify study and laboratory testing procedures.

Women in the study ranged from 19–43 years old, with a mean age of 29, and men ranged from 21–50 years old, with a mean age of 32. The three study cohorts were each randomized into three arms: Carraguard, placebo gel, or no product. In the cohort of sexually abstinent women, participants in the two gel arms were instructed to insert the gel every evening for 14 days. In the cohort of sexually active women, participants in the two gel arms were instructed to insert gel within one hour prior to sexual intercourse,

and once daily for days in which no intercourse occurred, for 14 days. All female participants were asked to visit the study clinic at Screening, Enrollment, Day 7, Day 14, and Day 21. In the male cohort, men in the two gel arms were instructed to apply gel to the penis every evening for seven days and to leave the gel on overnight. Male participants visited the clinic at Screening, Enrollment, and Day 7.

In general, adverse safety-related findings were rare among the participants in this trial, with no Serious Adverse Events (SAEs). Genital findings with either intact or disrupted epithelium were rare in women, with no significant differences between the study arms. Similarly, there were no genital findings among women in the no-product arm in either cohort; this could be a result of clinicians not being blinded to these participants' treatment assignment, and as a result inadvertently examining them less carefully than participants in the two gel arms. There were no genital findings in male participants in this trial.

Vaginal candidiasis was rare, though about half of the women in the sexually active cohort and a third of the women in the sexually abstinent cohort had incident bacterial vaginosis (BV) during the trial. However, since there were no statistically significant differences between study arms in the incidence or persistence of BV in either the sexually abstinent or sexually active cohorts, Carraguard use was not associated with abnormal vaginal flora. Few women had a clinically significant increase in cervico-vaginal lavage (CVL) viral load, and they were evenly distributed across study arms. CVL viral loads for two women in each arm increased significantly between days 0 and 7, and for one to two women in each arm between days 0 and 14. Therefore, exposure to Carraguard gel for 14 days did not increase HIV-1 RNA genital shedding in this study. For women, the most commonly reported symptoms during follow-up were vaginal discharge (40%), lower abdominal pain (23%), and increased urinary frequency (20%), with no differences between study arms. Male participants reported very few symptoms, with no significant differences between study arms.

In general, participants in all three cohorts reported high acceptability of study product use, with no significant differences between the cohorts of women. Among men in the sexually abstinent cohort, there was a significant difference between the two gel arms in participants' overall rating of the study product: 86% of men in one gel arm said they liked the study product very much, while only 33% of men in the other gel arm said they liked the study product very much (Fisher's exact p=0.04). Responses overall were positive or neutral, with almost no participants reporting disliking the gel overall or not liking particular characteristics of the gel.

Overall, there were no major differences between study arms in any clinical findings or self-reported symptoms in the three study cohorts, and Carraguard use was not associated with genital epithelial disruption or intact genital findings in women or men, abnormal vaginal flora in women, increased HIV genital shedding, or other abnormal clinical exam findings in women or men. This study was not designed to determine Carraguard efficacy or effectiveness; however, the study demonstrated that Carraguard is acceptable to and can be safely used by HIV-positive women and men.

Implementing Organization(s): South Africa Medical Research Council (I01.27A)
Population Council

Collaborating Organization(s): US Centers for Disease Control and Prevention

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Gel Production for Safety Study of Carraguard® Among HIV-Positive Women and Men

Part of project Number/s: **08300**
Country/ies: United States
Technical Coord.: Robin Maguire
Period: July 2001 – February 2003
Objective: To provide applicators containing the experimental microbicide Carraguard or a methyl cellulose placebo for a Phase 1 safety study among HIV-positive women and men in Durban, South Africa.

Activity Description:

The Center for Biomedical Research (CBR) produced the supply of Carraguard- and placebo-filled applicators necessary for "IPD: Phase 1 Safety Study of Carraguard (PC-515) Among HIV-Positive Women and Men."

Final Report:

The production of Carraguard and placebo gels for the safety study began with Population Council scientists at CBR conducting the required analytical chemical identification testing of active (carrageenan) and inactive ingredients. Analyzed raw materials were forwarded to Clean Chemical Sweden AB (CCS), the manufacturer of the gels and of the gel-filled applicators. The production process consisted of one manufacturing run of each gel (Carraguard and placebo). Gel production batches were tested for acceptable limit validation. Microbiological testing was conducted on both the bulk production batch and after the gel was filled in applicators. CBR scientists identified impurities and validated batch uniformity. These activities were carried out between July and December 2001.

Rigorous in-process control testing was instituted during the production development phase to ensure consistency among production batches and to ensure that no deviations occurred in the manufacturing procedure. Production samples were retained for product stability testing throughout the study (see "CBR: Stability Profiles for Carraguard and Methyl Cellulose Placebo"). Reserved samples are being maintained under controlled storage conditions until one year after their expiration date, which is currently being determined in the stability study.

A new randomization code was generated for the study, requiring an amendment to the packaging and shipping standard operating procedures developed for the Phase 2 trial. This involved changing packaging, labeling, and shipping instructions for the applicators, in collaboration with CCS. Protocols for each study dictate how packaging, shipping, and correspondence to various sites should be handled, identifying contact persons at each study site and at the Council. Packing and shipping of study supplies were completed during March 2002.

Activities related to this project continued into Year Four of the Population Council Program III. Owing to slow enrollment in the safety study, the study applicators containing Carraguard and methyl cellulose placebo, which had been shipped to the sites in March 2002, would have reached or would be nearing their expiration dates at the revised time of study completion. Therefore, new supplies were needed. Gel-filled applicators from the first Carraguard and methyl cellulose production batches for use in the upcoming Phase 3 efficacy trial were thus diverted to this Phase 1 HIV-positive study.

These new production batches underwent the same rigorous control testing as those produced during Year Three. The needed applicators passed the final acceptable limit and control testing criteria, were packaged in accordance with the randomization scheme as previously designed for this particular study, and were shipped to the clinical trial site in January 2003.

Implementing Organization(s): Population Council

Collaborating Organization(s): Clean Chemical Sweden

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

IPD: Phase 1 Safety Study of Carraguard® for Rectal Use

Project Number/s: **05606**
Country/ies: United States
Technical Coord.: Janneke van de Wijgert
Period: April 2002 – November 2002
Objective: To examine the safety and acceptability of Carraguard when used rectally.

Activity Description:

Any microbicide that becomes available is likely to be used during anal sex by both men and women, regardless of whether it is labeled or designed for rectal use. Thus it is important to determine the rectal safety and acceptability of any potential microbicide. This study will be conducted along the lines of a traditional Phase 1 safety study, in which a small cohort uses the product for a short period of time. Collaborators at Columbia University will recruit as study participants HIV-positive and HIV-negative men who have sex with men who are or are not engaging in receptive anal intercourse.

Final Report:

Protocol development work, most of which took place during Year Four of the Population Council Program III, included several meetings between Council staff and colleagues at Columbia University to address the inherent difficulties in assessing the rectal safety of any potential microbicide. Work on the protocol continued until November 2002, at which point Council management decided to put the rectal safety study on hold for several reasons. First, it was learned that the US Food and Drug Administration (FDA) may not require any additional rectal safety data over and above that from a small study (not funded by USAID) already conducted by scientists at the Council's Center for Biomedical Research. In addition, Council researchers consulted with other microbicide developers regarding their plans for assessing rectal safety. While many expressed their skepticism about the possibility of developing a microbicide that could protect people from HIV during anal sex, almost everyone agreed that vaginal microbicides will make a public health difference only if they are made available over-the-counter (OTC). While many microbicide developers think it is likely that the FDA will require some rectal safety data for OTC licensing of vaginal microbicides, this is not known for sure. Due to these uncertainties, the Council decided to wait until promising effectiveness data on a candidate vaginal microbicide were available before proceeding with rectal safety studies. To date, only a small amount of staff time budgeted for this project has been used. The remaining funds will be shifted to other studies.

Implementing Organization(s): Population Council

Collaborating Organization(s): Columbia University

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

Technical Assistance for the Council's Expanded Safety Study Assessing the Safety, Acceptability, and Preliminary Effectiveness of the Council's Lead Candidate Microbicide, Carraguard® (PC-515)

Project Number/s: **05601**
Country/ies: South Africa
Technical Coord.: Barbara Friedland
Period: October 1999 – September 2000
Objective: For Family Health International (FHI) to provide technical assistance for the expanded safety study of Carraguard in South Africa.

Final Report:

The International Programs Division is conducting a randomized, double-blind, multi-site, placebo-controlled study of Carraguard in South Africa. FHI provided technical assistance through a subaward, helped organize and plan the study training in Year One, and assisted in monitoring the study.

In September 2000, Patti Bush traveled to the University of Cape Town and Medical University of Southern Africa sites with Kelly Blanchard to conduct a quality assurance audit. The scope of the visit included review of study systems (e.g., screening, enrollment, documentation, participant follow-up, adverse events, clinical supply storage, product accountability records, and so forth). A detailed site visit report is on file at the Population Council and at FHI.

Implementing Organization(s): Family Health International (FHI) (I99.117A)
Collaborating Organization(s): Medical Research Council
Medical University of Southern Africa
University of Cape Town

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Reproductive Toxicology: Segment I and Segment II for Carraguard®

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2001 – December 2003

Objective: To ensure the safety of Carraguard when used by women of childbearing age.

Activity Description:

Reproductive toxicology profiles, required by the US Food and Drug Administration (FDA) for all drug products, are of particular importance for Carraguard. Because Carraguard is a noncontraceptive microbicide, it can and will be used by women who wish to conceive while protecting themselves and their sexual partners against infection by HIV and other sexually transmitted pathogens. Therefore, it is essential that use of the product has no adverse effects on either male or female fertility or on embryonic development pre- and postimplantation. Segment I reproductive toxicology studies, which are conducted in rats, will determine whether Carraguard has any effect on fertility or a teratogenic effect on early embryonic development through implantation. Segment II studies, which, as required, are conducted in both rodent (rat) and nonrodent (rabbit) species, will evaluate embryonic development through birth.

Final Report:

The Therimmune Research Corporation conducted a three-month Segment 2 reproductive toxicology study designed to provide data on the potential maternal and/or developmental toxicity of Carraguard administered vaginally during the period of organogenesis [Gestation Days (GD) 7-19] in the pregnant rabbit. The effects of both one and three daily applications of Carraguard were evaluated. Therimmune provided a final study report in June 2004.

Therimmune found that Carraguard treatment had no biologically significant effect on mortality, clinical observations, food consumption, gross pathology, gravid uterine weight, pregnancy status or fetal body weights. Administration of Carraguard three times daily resulted in subtle signs of maternal toxicity as evidenced by abortion, body weight loss during GD 7-10, higher post-implantation loss, and increased incidence of fetal malformations. While individually none of these parameters are statistically significant, the combined incidence may be attributable to both the high viscosity and the high vaginally administered volume dose and not a result of toxicity associated with the drug substance.

Therefore, under the conditions of this study, the no observable adverse effect level (NOAEL) for maternal and embryo/fetal toxicity was 1 dose of Carraguard daily. The lowest observable adverse effect level (LOAEL) was 3 doses of Carraguard daily. Carraguard did not appear to be teratogenic in the New Zealand White Rabbit, as embryo/fetal toxicity was only observed at a maternally toxic dose.

Implementing Organization(s): Population Council

Collaborating Organization(s): Covance Laboratories
Therimmune Research Corporation

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Phase 3 Documentation and Production Start-Up

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2001 – July 2002

Objective: To finalize manufacturing documentation for the chemistry, manufacturing, and controls (CMC) file for Carraguard®.

Activity Description:

In order to receive US Food and Drug Administration (FDA) approval for the production of Carraguard for the Phase 3 efficacy trials, the CMC file must be completed in accordance with the final production procedures used for marketing the approved drug. The final procedural scale up of manufacturing for Carraguard was completed in mid-2001. This activity comprises preparing documentation of all finalized manufacturing records.

Commercial relationship: Clean Chemical Sweden

Final Report:

All CMC documentation has now been completed. The development and finalization of standard operating procedures (SOPs) was a key component in assembling complete Phase 3 documentation. SOPs for water purification, equipment operation, cleaning and maintenance of equipment, sampling of tap water used in equipment line clearance and cleaning, maintenance and operation of buildings and facilities, and quarantine of materials and products pending acceptance or rejection have been finalized and approved. Additional SOPs for production performance qualification and cleaning validation were written and approved and have been added to the SOPs of the production protocols for Carraguard and placebo.

Three additional SOPs were finalized as well. One was for the identification of analysis for the raw materials. This SOP was delayed when responsibility for conducting chemical analysis of all formulation ingredients except PDR98-15 (the carrageenan used in the manufacture of Carraguard) was transferred to Clean Chemical Sweden AB (CCS) by the terms of the renegotiated manufacturing contract. It was necessary for CCS to expand its laboratory facility in order to fulfill this contract. The other two SOPs are those for applicator filling and packaging/shipping. The decision to have each applicator printed with a bar code initially created delays in the completion of these SOPs, however, the use of bar-code technology has significantly aided in streamlining the drug accountability process for the Phase 3 trial and may help with behavioral research as well.

Documentation has been finalized for the closeout of previous production files for inventorying raw materials, handling incoming raw materials, and handling and storing packaging materials. All Phase 2 expanded safety and acceptability study sites (except for the site of the ongoing "IPD: Phase 1 Safety Study of Carraguard [PC-515] Among HIV-Positive Women and Men") have completed their site closeouts and have completed documentation for drug accountability reports. Procedures for production controls, sampling of batch samples and finished products, and microbiological testing have been finalized. The stability testing procedures and final protocol were developed in early 2003 and have been implemented (see "CBR: Stability Profiles for Carraguard and Methyl Cellulose Placebo").

Production documentation has been completed. It will be submitted to the FDA and the European Agency for Evaluation of Medicinal Products (EAEMP) for review, with final approval to come from the FDA.

Certification of the production facility was made by Läkemedelsverket (Swedish Medical Agency), which inspected it after an expansion and upgrade for compliance with FDA and European Union regulations for pharmaceutical manufacturing. (The upgrade was not funded by the Population Council.) Läkemedelsverket certification is recognized and accepted by the FDA and the EAEMP.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard®

Project Number/s: **05604**
Country/ies: South Africa
Technical Coord.: Barbara Friedland
Period: July 2001 – January 2005
Objective: To increase the capacity at existing Phase 2 trial sites in South Africa, develop informed consent (IC) and educational materials, and establish community advisory groups (CAGs) for a Phase 3 Carraguard trial.

Activity Description:

A Phase 3 trial of Carraguard will be conducted at existing Phase 2 sites in South Africa – UCT and Medunsa – and at the Medical Research Council. Beginning in July 2001 and until the Phase 3 trial begins in March 2004, project staff will work to increase the capacity at the existing study sites in terms of personnel, space, and other resources. An integral part of preparing for the Phase 3 trial involves determining how best to obtain informed consent (IC) from study participants and how to educate the communities from which they come. Phase 2 trial IC procedures will be reviewed and evaluated prior to designing materials for Phase 3. A video will be developed, and the study information booklet designed for the Phase 2 trial will be adapted for Phase 3. To educate the community, local consultations among stakeholders (government officials, activists, and advocates) will be held in South Africa prior to beginning Phase 3. In addition, community advisory groups (CAGs) will be established at the trial sites, as appropriate, to serve as a bridge between the community and the research team.

Beginning in Year Four, for administrative reasons, Population Council in-house costs for this activity were moved to the activity "IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard." Items remaining budgeted under this activity were the subawards to trial sites, contracts to the producers of the IC video and booklet, and payments to consultants and translators for IC materials.

Final Report:

The major accomplishments of this activity matched the objectives: capacity was substantially increased at the existing Phase 2 trial sites in South Africa, IC and educational materials were developed, and CAGs were established. Study start-up, originally slated for the spring of 2002, was delayed until March 2004 due to a number of factors, including debates in the microbicides field over whether to use a two-arm or three-arm study design (that is, on whether to include a no-product/condoms-only arm).

In July 2001, subawards were issued to the University of Cape Town (UCT) and the Medical University of Southern Africa (Medunsa) to scale up operations at the sites between the completion of the Phase 2 expanded safety trials and the commencement of the Phase 3 efficacy trial. In September 2001, the UCT study team secured new clinic and office space at the Uluntu Centre, an existing office complex in Gugulethu. Renovations of this space, now called the "Empilsweni Centre for Wellness Studies," were completed in May 2002, enabling more than 2,000 women to be enrolled at that site.

At Medunsa, the original plan was to have two clinics: one in the township of Soshanguve, and a second based at the University in Ga Rankuwa, each of which would enroll approximately 1,000 participants. The Soshanguve clinic, which is being leased to the study by the Department of Public Works, required major renovations, including a revamping of the sewage system. The renovations were completed and the clinic,

called the "Setshaba Research Centre," opened in June 2004. Because of difficulties in securing the second site, Ga Rankuwa, more than 2,000 women will be enrolled at Soshanguve. However, the Ga Rankuwa site is still being used for recruitment. (Medunsa is now called the University of Limpopo, Medunsa Campus.)

In addition to the structural work at the UCT and Medunsa sites, a large effort was undertaken to educate the affected communities about the upcoming trial in order to pave the way for a smooth recruitment process and to create an atmosphere of transparency between the study team and the community. Both sites established CAGs after a series of stakeholder meetings had been held in the communities. CAG members include local community leaders, members of NGOs, activists, and health authorities. The CAGs were particularly instrumental in advising on the content and format of the IC video and study booklet, discussed below. The CAGs met frequently from the time they were established until the trial began in March 2004, and now meet on an ad hoc basis as issues arise. Meetings can be called by CAG members or by study staff.

A major emphasis during scale up was the production of a video and study booklet, which are key components of the IC process. Pandamonium Productions was selected in a competitive bid to collaborate with the educational materials team (comprising staff at the Population Council, UCT, and Medunsa) to develop the script and produce a 20-minute video in English, Tswana, and Xhosa. A portion of the video was pre-tested in the recruitment communities by Clacherty and Associates. The script was revised based on the results of pre-testing, input from the CAGs, and feedback from the Population Council's Institutional Review Board. The video was completed in December 2003. The study booklet was designed by Glynis Clacherty, of Clacherty and Associates, in collaboration with the educational materials team. The booklet is an expanded version of the IC form, with pictures and analogies added to explain difficult concepts. After pre-testing and review by the CAGs, the booklet was printed in English, Tswana, and Xhosa in January 2004. In addition to the centrally-developed video and booklet, site-specific recruitment materials such as posters and brochures were developed at UCT and Medunsa under this activity. After the Durban trial site was added, Zulu versions of the video and booklet were produced.

Study staff at all three sites have noted that the video has been very helpful in explaining the study to potential participants and that women understand much more by the time they are in the position to decide whether to sign the IC form as compared with previous trials. In addition to being critical for recruitment, the video proved to be an extremely useful tool for training study staff. The booklet also has been useful for explaining the study to potential participants, their partners and families, and members of the community.

A formal evaluation of the IC process, with a focus on the impact of the video, is currently underway, and is being funded under the Population Council Product Development Cooperative Agreement.

Implementing Organization(s): Medical University of Southern Africa (I01.85A)
University of Cape Town (I01.81A)
Clacherty and Associates (CI02.58A)
Pandamonium Productions (CI02.22A)
Population Council

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard®

Project Number/s: **05607**
Country/ies: South Africa
Technical Coord.: Barbara Friedland
Period: July 2002 – June 2008
Objective: To determine the efficacy and long term safety of Carraguard®.

Activity Description:

The management of this activity was transferred from the International Programs Division (IPD) to the Center for Biomedical Research (CBR) during Year Four of the Population Council Program III (see "CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard®"). IPD staff, however, continued to be involved in the implementation of the Phase 3 trial, including developing the study protocol and case record forms (CRFs) and carrying out the overall planning for the trial. IPD staff also continued to be involved in the ongoing management of the behavioral aspects of the trial, including chairing behavioral committee meetings and spearheading efforts to deal with challenges as they arose (such as gel adherence issues).

Additionally, this activity includes IPD's continued involvement in scale-up activities, including renovations at the study sites and development of educational materials (see also "IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard®"). IPD continues to be involved in developing and testing informed consent forms and educational materials. In an effort to adhere to the highest ethical standards, the informed consent forms and the process of obtaining informed consent, which includes use of a study booklet and a video, will be evaluated before and during the Phase 3 trial.

Final Report:

Since the Phase 3 efficacy trial of Carraguard is ongoing, the overall objective of this activity, namely, determining the efficacy and long-term safety of Carraguard, has not yet been achieved. However, we have accomplished several important objectives in the areas of counseling and informed consent.

In 2004, a behavioral team consisting of members from each of the three study sites – University of Cape Town (UCT), Medical Research Council, and University of Limpopo, Medunsa Campus – and staff from the Population Council developed a study-specific counseling manual to be used by counselors during all interactions with study participants. The purpose of this manual is to ensure consistent messages from all counselors to all study participants. The manual addresses gel and condom use, family planning, HIV pre- and post-test counseling, and ongoing informed consent. The manual also includes reference material with detailed information on the symptoms and treatment of sexually transmitted infections, family planning options, and condoms (including instructions for use and information on condom efficacy). Relevant sections were translated into the major languages spoken at the study sites: Tswana, Xhosa, and Zulu. The behavioral team also developed a standard operating procedure (SOP) for evaluating the counseling process. Counselors at each site will be evaluated twice a year to ensure they are adhering to the counseling protocol and providing appropriate support to study participants.

One of the priorities of the behavioral team has been the development and implementation of the informed consent process. The team developed an SOP for informed consent which outlines the process and materials to be used throughout the trial, beginning at recruitment. Two recruitment scripts were developed:

one for use at recruitment venues where the video is shown, and a slightly different version for use at venues where the video is not shown. These standardized scripts ensure consistent study introduction to all participants at all sites. The team also developed a set of questions to assess participants' comprehension prior to signing the informed consent form. A similar set of questions assessing comprehension is used during subsequent counseling sessions. Finally, a guide was developed for study staff to use during group review of the informed consent form. Study staff members read through the consent form with a small group of women to ensure that all potential participants – even those who cannot read – have heard all the information before meeting with a study staff member on a one-on-one basis to ask questions, and before signing the informed consent form (if they choose to participate in the study).

An evaluation of the informed consent process at UCT and the University of Limpopo is now underway. The protocol for this evaluation was drafted by staff at the Population Council, with input from the study sites. The evaluation comprises two parts: an assessment among the recruitment population, and another assessment among enrolled study participants. To assess whether the video has an impact in the recruitment population on comprehension and willingness to participate, we are comparing groups of women who were recruited at sessions where the video was shown with groups of women who were not shown the video at recruitment. To assess the overall level of comprehension among enrolled study participants, women are interviewed at the conclusion of their enrolment visit.

The Community Agency for Social Enquiry (CASE), based in Johannesburg, is implementing this assessment of the informed consent process. A training was held in June 2005 which included the fieldworkers who are implementing the study at UCT and the University of Limpopo, staff from CASE, the co-investigators from UCT and the University of Limpopo, and staff from the Population Council. Because enrolment in the Phase 3 trial has slowed since the informed consent evaluation protocol was written, data collection will take longer than anticipated. Therefore, while we had hoped to complete data collection in July, our current projection is that it will not be completed until October 2005. We also intend to add a qualitative component to this evaluation, which will be conducted under the Population Council Product Development (PCPD) Cooperative Agreement, to assess study staff members' opinions about the impact of the video.

The work from this activity is continuing under the PCPD, under the activities "Developing Informed Consent and Recruitment Materials for Population Council Microbicides Trials" (project #44211); "Evaluating and Improving the Informed Consent Process in Microbicides Clinical Trials" (project #44212); and "Carraguard® Clinical Development: Large-Scale Phase 3 Efficacy Trial" (project #08301).

Implementing Organization(s): Community Agency for Social Enquiry (CASE) (I05.25A)
Population Council

Collaborating Organization(s): Medical Research Council
University of Cape Town
University of Limpopo, Medunsa Campus

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard®

Part of project Number/s: 08300

Country/ies: South Africa

Technical Coord.: Stephanie Skoler

Period: September 2002 – June 2008

Objective: To determine the efficacy and long-term safety of Carraguard®.

Activity Description:

The Phase 3 efficacy trial of Carraguard commenced in the first quarter of 2004 and is being implemented at three sites in South Africa. The main objective of the trial is to determine whether use of Carraguard protects women from HIV infection. Work on educational materials has been carried out under the "IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard" activity.

Female volunteers are recruited from family planning and general health clinics according to site-specific recruitment plans. Eligible women are HIV-negative at screening, sexually active, and not pregnant or planning to become pregnant for the duration of the trial. There are two study arms: Carraguard gel and condoms, and methyl cellulose placebo gel and condoms (all women are instructed to use the gel together with condoms). Participants at each study site are randomized to one of the two study arms. 6,639 women will be enrolled over a two year period. Each woman will participate for up to two years, and the trial will take place over three years. Women are asked to insert the study gel into the vagina prior to every act of vaginal intercourse, but not to use it orally or rectally. Women are asked to return to the clinic regularly for pelvic exams, STI testing and treatment for curable STIs, HIV and safer-sex counseling, interviews about adherence, and to receive more study supplies. Applicators are tested to help determine gel usage.

The Population Council coordinates the trial, which is being implemented at the University of Limpopo/Medunsa Campus (formerly MEDUNSA), University of Cape Town (UCT), and the Medical Research Council, South Africa (MRC). The Council performs data management and safety adjudication, ensures that ethical and regulatory needs are met and that proper monitoring is in place; conducts trainings; facilitates communication between staff; and reports to donors and other stakeholders. The Council provides funding and oversees the administration of the trial sites.

Final Report:

The Phase 3 efficacy trial of Carraguard began in March 2004. The main objective, to determine the efficacy and safety of Carraguard, has not yet been achieved since the study is ongoing. However, significant progress is being made; as of August 31, 2005, 6,976 women had been screened and 4,361 had been enrolled – overall enrolment rates have surpassed expectations – and recruitment is ongoing.

Several notable milestones enabled the accomplishment of trial implementation, despite the challenges which delayed study commencement. The two-arm protocol was finalized in September 2003 after being delayed by a lengthy debate in the microbicide field regarding whether Phase 3 trials should include a 'no gel' (condoms only) arm. Standard operating procedures (SOPs) and Case Report Forms (CRFs) were finalized in early 2004. The Medicines Control Council (MCC, the regulatory body of South Africa) and all relevant ethics committees granted the approvals, however, some of the approvals were delayed due to administrative issues, which postponed study start-up. In April 2005, the protocol was submitted to the U.S. Food and Drug Administration (FDA), which returned comments in August. Dialogue with the FDA is ongoing.

Initial training on the protocol and CRF completion was conducted at UCT and MEDUNSA in March 2004. The training was repeated in July 2004 at the MRC, which joined the study team later than the other sites. Subsequently, informal training (via quality assurance) and formal refresher trainings on the protocol and various relevant disciplines (clinical, counseling, laboratory and Good Clinical and Laboratory Practices) were conducted. Refresher trainings will continue throughout the trial to ensure the utmost ethical and regulatory compliance and to simultaneously build capacity at the sites.

In order to ensure quality management of the significant amount of incoming data, the data management system Datafax was purchased. DataFax, which enables data entry via fax (thus circumventing the unreliable internet access in South Africa), is low-tech at the study sites; is modestly priced as compared to other competitive systems; and allows ongoing data entry and review, facilitating timely data cleaning and minimizing time to database lock for analysis at the end of the trial. As of August 31, 2005, over 175,000 CRFs had been received and reviewed by the data management team in New York. To facilitate the tracking of approximately 2 million applicators, a custom-designed barcode system was developed. Using this system, the sites control applicator receipt, distribution, and return; identify and address gel sharing; track participant visits; and streamline overall clinic management. Finally, to help determine applicator usage, the Phillips Laboratory at CBR developed a low-tech test that can rapidly determine if an applicator has been inserted into the vagina. This test is the first biological marker to be employed in a microbicide trial to measure usage. The test has been validated and implemented at all three sites, and all applicators returned opened are tested to determine gel usage. Results will be used to identify an adherent subset of the population for a per-protocol analysis.

Study implementation has resulted in benefits for the participating communities. Participating women have been counseled on safer sex; tested for HIV, STIs and cervical cancer, and treated or referred for these conditions as needed; and recruitment sessions have raised awareness regarding HIV even among men and women not participating in the trial. These benefits will continue throughout the duration of the trial.

On August 29, 2005, the first Data Safety Monitoring Board safety review was held, and it was recommended that the study continue. No findings are yet available since the study is ongoing. The trial is continuing with support from the Population Council Product Development Cooperative Agreement and the Bill and Melinda Gates Foundation. Participant follow-up is expected to be completed in 2007, and the final study report will be completed in 2008.

Implementing Organization(s): Medical Research Council (CB04.105A)
Medical University of Southern Africa (CB04.103A)
University of Cape Town (CB04.101A)
Medical University of Southern Africa (CB03.103A)
University of Cape Town (CB03.101A)
Population Council

Collaborating Organization(s): Clindev (Pty) Ltd
Lancet/BARC

Activity Funding: HIV/AIDS Core

Contribution to Results Framwork: IR 1.3

CBR: Carraguard® and Placebo Production for Phase 3 Efficacy Trial

Part of project Number/s: 08300
Country/ies: United States
Technical Coord.: Robin Maguire
Period: April 2002 – June 2007
Objective: To implement gel production for the Phase 3 efficacy trial of Carraguard.

Activity Description:

Approximately 2 million gel-filled applicators – 1 million each of Carraguard and placebo – will be needed for the Phase 3 efficacy trial of Carraguard. Approximately 18 production runs for each gel will be necessary over a three-year period. The repeated production runs and the staggered production scheduling will necessitate the execution of rigorous and extensive control and analytical testing. (The procedural development of the production protocol, controls, and analytical tests was completed prior to July 2001, and the validation and documentation were included as part of the "CBR: Phase 3 Documentation and Production Start-Up" activity.)

A large portion of the initial Phase 3 gel production will occur prior to the commencement of the clinical trials in order to ensure that sufficient supplies of gel are stockpiled. Staggered production throughout the trial will allow for any necessary production reruns and will also allow for increasing or decreasing production according to the actual numbers of applicators used by study participants. Additional benefits of the staggered production schedule include increased convenience in obtaining and analyzing active and inactive ingredients; scheduling of production and filling equipment; microbiological, impurity, and acceptability control testing; and packaging and warehousing of accepted and released products. The early production runs and validation and release of study gels will ensure that study sites are well-stocked.

Commercial relationship: Clean Chemical Sweden (CCS), manufacturing

Final Report:

Phase 3 gel production commenced in 2002. Initial production planned for the manufacture of sufficient quantities of each gel type in order to implement the five-year stability profile (see "CBR: Stability Profiles for Carraguard and Methyl Cellulose Placebo"), and to stock the clinical trial sites prior to the commencement of the Phase 3 trial. This required the production of three batches of each gel type. All study gel batches have had to comply with control testing criteria, which include ensuring that the gel is free of impurities, that it meets chemical and physical parameters, and that it is either biologically active (Carraguard) or inactive (methyl cellulose). Gel production has continued in pace with study needs.

Upon completion of the final procedural scale-up of manufacturing for Carraguard in early 2003, the manufacturing documentation for the chemistry, manufacturing, and controls (CMC) file for Carraguard was completed in accordance with the final production procedures that will be used for marketing the approved drug. All documentation is compliant with Good Manufacturing Procedures (GMP) as set forth by the U.S. Food and Drug Administration (FDA). In addition to Carraguard and methyl cellulose placebo production protocols, the documentation includes: (1) standard operating procedures (SOPs) for material receipt and handling, water purification, equipment operation, cleaning and maintenance of building and facilities, quarantine, identification analysis, applicator filling, and packaging and shipping; (2) previous production files for inventory of raw materials and finished products, production runs, out-of-

specifications, and distribution logs; and (3) validation of control methodology for acceptable limits and controls, lot and batch consistency, microbiological testing, stability profiles, analytical identification, and production protocols.

A custom-designed randomized barcode system was created for the Phase 3 trial, requiring an amendment to the SOP (which had been developed for the Phase 2 trial) for the packaging, labeling, and shipping of the applicators. This amendment was completed with the collaboration of CCS. The barcode scheme eases the burden of tracking the estimated 2 million applicators for the study. A unique barcode is assigned to each production batch of gel, and the corresponding barcode is printed on all applicators generated from that batch. Applicators are then packaged into study boxes, which are sealed with the corresponding barcodes, for distribution to the participants. The barcode system is further utilized to facilitate both product management and site management (see "CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard").

Communication with the FDA regarding manufacturing process documentation is ongoing. In order to fulfill the Phase 3 trial gel needs, this activity will continue through June 2007 with funding from the Population Council Product Development Cooperative Agreement.

Implementing Organization(s): Population Council

Collaborating Organization(s): Clean Chemical Sweden

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Stability Profiles for Carraguard® and Methyl Cellulose Placebo

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2002 – February 2009

Objective: To establish a five-year stability profile for Carraguard and a Phase-3-trial-duration stability profile for methyl cellulose placebo.

Activity Description:

Five-year stability testing will be conducted on Carraguard in order to optimize its appeal as an over-the-counter (OTC) product and to minimize its final pricing once it has been proven to be an effective microbicide and has been approved by the U.S. Food and Drug Administration (FDA). Thus far, Carraguard has undergone two-year stability testing with very encouraging results. Results have indicated no change in the physical appearance of the filled applicators or their gel contents nor any change in the pH, viscosity, or microbicidal strength of the formulation when stored under an extreme range of temperatures and humidity conditions. However, similar results were not found in evaluating the stability of the methyl cellulose placebo. Under storage conditions of 40˚C±2˚ and 75 percent±5 percent relative humidity, the placebo exhibited deterioration of gel integrity, including change in physical appearance and decrease in pH and viscosity. Fortunately, a placebo need only remain stable for the duration of its use in clinical studies. Therefore, stability studies will be conducted such that a five-year stability profile can be obtained for Carraguard and a stability profile can be obtained for methyl cellulose placebo sufficient for its use for the duration of the Phase 3 trial.

Final Report:

Between July and September 2002, Clean Chemical Sweden AB (CCS) and the Population Council finalized the logistics for sample labeling, storage of samples prior to testing, random selection of stability samples, and procedures for notification and distribution of samples to testing personnel at CCS and the Council. The stability protocol and necessary standard operating procedures (SOPs) were developed in accordance with the FDA's guidelines entitled "Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products." In addition, the Council developed a secure electronic filing system to record stability test results.

Because gels being tested for stability at the Council are identified by bar codes, a system was developed so that identification of gel type by bar code was not possible by Council researchers. More importantly, it was decided that the resulting data would not be stored in any electronic file that could be accessed directly by study researchers or staff of the Council's Information Technology department, who service the electronic files of CBR and clinical development staff. A complex scheme was developed that would allow for electronic capture and storage of data, and a special SOP was established for this process.

Initially, stability testing was to be conducted on batches from the first round of gel production (September–November 2002), but samples from these batches yielded conflicting results in preservative challenge testing. Challenge testing involves exposing a product to specified microorganisms to ascertain the ability of the product to resist contamination. It was decided to increase the amount of preservative in Carraguard to resolve any doubt that Carraguard was suitably protected from microbial contamination. Because the formulation had changed, further stability testing on the 2002 test samples was discontinued in September 2003.

Stability testing resumed following the successful completion of three acceptable back-to-back production batches for both the reformulated Carraguard and the methyl cellulose placebo (the three production batches were completed between December 2003 and February 2004). The procedure for sample selection, labeling, and storage remained unchanged. All three batches of Carraguard and methyl cellulose gel passed stability testing at the one-year time points.

Since it was necessary to restart the production and stability testing for the five-year profile in 2003, the activity will continue through February 2009, with funding from the Population Council Product Development Cooperative Agreement.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Rectal Safety of OTC Lubricants

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: David M. Phillips

Period: July 2002 – June 2003

Objective: To evaluate the cytotoxicity of over-the-counter (OTC) lubricants to determine which ones would be safe for use during rectal intercourse.

Activity Description:

Population Council researchers have demonstrated that rectal use of nonoxynol-9 (N-9) causes mice to be greater than 20 times more susceptible to infection by herpes simplex virus type 2 (HSV-2) following rectal challenge. Using microscopic methods, researchers in David Phillips's laboratory have shown that mice are apparently more susceptible to virus infection because N-9 causes sloughing of the protective rectal epithelium. In two separate follow-up studies it was found that rectal application of N-9 in humans causes massive sloughing of the rectal epithelium. In an independent evaluation, another laboratory obtained similar results in monkeys. Thus it appears clear that N-9 products are likely to be hazardous if employed during rectal intercourse.

A survey of men who have sex with men concluded that 80 percent of the survey participants use lubricants, and 40 percent choose lubricants containing N-9. Exfoliation of the rectal epithelium with use of products containing N-9 is likely to increase the chances of infection by HIV and other sexually transmitted pathogens in people. In addition, although many other lubricants used during rectal intercourse do not contain N-9, they may contain various preservatives—including chlorhexidine and benzalkonium chloride—that are potentially toxic if used rectally. Lubricants are classified by the US Food and Drug Administration (FDA) as cosmetics and have not been strictly regulated for rectal toxicity. Therefore, the goal of the proposed work is to determine which lubricant(s) do not cause damage to the rectal epithelium, thereby being preferable for use during rectal intercourse.

Final Report:

During Year Four of the Population Council Program III studies were conducted to determine the relative toxicity (safety) of various sexual lubricants for rectal use that do not contain N-9. In order to determine the relative safety, sexual lubricants were assayed for cytotoxicity using the MTT assay, effect on herpes simplex virus 2 (HSV-2) infection following vaginal challenge, effect on HSV-2 infection following rectal challenge, and effect on sloughing of epithelial cells from the rectal mucosa. The rectal sloughing assay, performed by counting cells in a lavage sample, is used to get a direct indication of disruption to the rectal epithelium. This particular assay proved to be very useful in establishing the relative degree of cytotoxicity among lubricants.

Formulations tested were Astroglide®, DeLUBE®, Vagisil®, ViAmor®, Carraguard®, and methyl cellulose. In addition, phosphate buffered saline and K-Y Plus® were used as negative and positive controls. Judging from the results of the four different assays, it is predicted that DeLUBE and K-Y Plus would be most likely to damage the rectal epithelium, while Astroglide, Vagisil, and ViAmor would cause some rectal damage. In contrast, Carraguard and methyl cellulose were not toxic in any of the assays. Because the rectal epithelium is fragile, Council researchers reason that toxic lubricants may breach the protective epithelial barrier and expose the underlying tissue to HIV or other sexually transmitted pathogens.

A manuscript describing this work, "Relative safety of sexual lubricants for rectal intercourse," has been submitted for review.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

Development of Microbicide/Spermicide Containing Lignosulfonic Acid (LSA)

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: David Phillips

Period: October 1999 – August 2000

Objective: To develop a novel microbicide that would have contraceptive properties in addition to protecting against sexually transmitted pathogens.

Final Report:

Efforts at the Center for Biomedical Research (CBR) have been directed toward the development of a novel microbicide that would have contraceptive properties in addition to protecting against sexually transmitted pathogens. The formulation is a combination of three active ingredients: nonoxynol-9 (N-9), the most common over-the-counter (OTC) spermicidal agent, and two antiviral ingredients—carrageenan, a sulfated polysaccharide extracted from seaweed, and lignosulfonic acid (LSA), a sulfated polymer extracted from wood pulp. Our main focus for the past year has been to determine if a combined formulation of LSA/carrageenan/N-9 (LCN) would be stable and nontoxic, thereby lending itself to development as a contraceptive microbicide with increased efficacy.

As stability is an essential parameter of a microbicide we initiated the following studies first: Formulations containing single active ingredients and various combinations were evaluated along the stability parameters of change in the formulation's visual appearance, pH, or viscosity, as well as any decrease of efficacy in protecting mice from HSV-2 infection. Baseline formulations of LSA and N-9 were formulated in methyl cellulose, as methyl cellulose has previously been shown to have no efficacy in protecting against HSV-2 infection and has a viscosity within the range of OTC vaginal products. All combination formulations consisted of the addition of active ingredients into carrageenan, which naturally yields an acceptable viscosity.

The efficacy studies in mice showed that the addition of either LSA or N-9 to carrageenan increased the rate of protection from HSV-2 infection, with the LSA/carrageenan combination significantly more efficacious. However, due to formulation difficulties (see below), the baseline efficacy rate of the LCN combination formulation was not determined.

Initial studies that developed combination formulations showed that when LSA is added to carrageenan the resulting viscosity is decreased in a dose-dependent manner, which is due to the inherent dispersing nature of LSA. This characteristic may prove to be beneficial by allowing for the concentration of carrageenan to be increased. The LSA/carrageenan formulation has maintained the stability parameters at storage temperatures of 25°C and 40°C over the nine-month testing period. (The 40°C results represent an accelerated time of approximately 18 months.)

When the LCN combination formulation was being developed, the formulation displayed a thixotropic phenomenon. Thixotropy is a decrease of viscosity due to shearing forces exerted on a formulation. Thereby, the formulation would be quite viscous when it was stationary and undisturbed. However, any disturbance produces liquefaction. A common example of a thixotropic formulation is ketchup. With ketchup, as liquefaction occurs the solvent has a tendency to separate from the solute. Similarly, over the stability test period, the thixotropic formulation exhibited a decrease in homogeneity, thereby indicating that a reformulation technique needs to be explored.

During the timeframe of these studies, the findings of the Col 1492 study were released. Preliminary results indicate that the study arm using the N-9–containing formulation, Advantage S, exhibited a significantly higher rate of HIV seroconversion than the control arm using the non-N-9 lubricant Replens®. In addition, a recent study evaluating another N-9 formulation, Conceptrol® has been halted due to an increased incidence of vaginal irritation equal to or greater than the outcome limit for discontinuance. In light of these studies and the difficulties with formulation stability, the development of a contraceptive formulation containing N-9 has been halted.

In order to obtain a rapid determination of any toxicological effects that might be a result of a previously unknown compound, a protocol was developed to serve as an easy, short-term evaluation for toxicology and carcinogenicity. The protocol set forth an acute dosing regimen that will introduce the compound under investigation at exposure levels of 100 and 400 times above those recommended for use. Toxicity and carcinogenicity parameters evaluated are changes in body conditioning and/or psychological behavior, any abnormal change in body weight and/or food consumption, and an increase in mortality rate. Additionally, circulating blood counts are compared at baseline and completion, and necropsy will determine if any gross lesions are observed in the vaginal areas. Weights of major visceral systems are measured to differentiate any significant abnormal changes compared to control groups or baseline. The protocol was reviewed and approved by The Rockefeller University Institutional Animal Care and Use Committee (IACUC) in accordance with the Association for Assessment and Accreditation of Laboratory Animal Care. Unfortunately, due to the instability of the LCN combination a toxicological evaluation could not be performed.

Future endeavors in developing a contraceptive microbicide will involve evaluation of other compounds for contraceptive properties that would prove to be nontoxic and compatible with LSA/carrageenan.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Development of a Nonsurfactant Contraceptive Microbicide

Part of project Number/s: 08300
Country/ies: United States
Technical Coord.: David M. Phillips
Period: January 2002 – June 2003
Objective: To develop a safe and effective contraceptive microbicide formulation.

Activity Description:
Although some microbicides currently under development are being designed to have contraceptive properties, none of the active ingredients thus far has been proven to be effective and safe for continual use. Consequently, the only dual protection method that has been proven effective is the male condom, which many men do not like, making negotiation of its use difficult for women. Therefore, there is a need for a method that is effective as both a microbicide and a contraceptive and that is safe (i.e., nontoxic) for continual use. The Population Council is well positioned to develop such a product by combining the steroid hormone Nestorone® with Carraguard®, since both Carraguard (CARRA) and Nestorone (NES) have been approved by the U.S. Food and Drug Administration (FDA) for vaginal use in clinical trials.

Final Report:
Initial activity on this project involved optimizing the CARRA/NES contraceptive microbicide to determine the compatibility and preliminary stability of the combined formulation and to ensure optimal release and diffusion of NES from the formulation. Because the steroid hormone NES is not soluble in an aqueous solution, two different solvents, dimethyl sulfoxide (DMSO) and ethyl alcohol (EtOH), were used and their impact on formulation integrity was evaluated. CARRA/NES formulations containing different concentrations of NES dissolved in either DMSO or EtOH were produced and stored under real and accelerated conditions. At set time points over a six-month period, samples were inspected for changes in appearance, pH, and viscosity. No changes were observed in any of the formulations or conditions. Additional parameters used to evaluate CARRA/NES component stability included measurements of the retention of Carraguard activity and relative strength, and the monitoring for possible degradation of NES.

Additionally, drug kinetic profiles were carried out with an *in vitro* dialysis system and *in vivo* rat studies. Results from the dialysis studies indicate that NES is released from the CARRA/NES formulation over a 12-hour period with the highest release within the first four hours. Results from the *in vivo* rat studies are similar, however the NES release occurs more evenly over time *in vivo*.

Another study, undertaken in collaboration with the Department of Obstetrics and Gynecology at the University of Uppsala, Sweden, has focused on the comparison of NES release levels in women at various time-points for up to 96 hours following a single vaginal application of CARRA/NES. *In vivo* results confirm the bioavailability of NES, and that it is released from Carraguard in sufficient levels during the first eight hours following application in order to support its development as an "on demand dual protection" method.

Because USAID requested that no further funds be spent on this activity after June 2003, additional proposed studies have not been completed.

Implementing Organization(s): Population Council
Collaborating Organization(s): University of Uppsala
Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Preclinical Studies for Second-Generation Microbicides

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2002 – June 2004

Objective: To advance an improved carrageenan-based second-generation microbicide into clinical testing.

Activity Description:

Over the last few years, Council researchers have been investigating methods of modifying carrageenan to improve its effectiveness, broaden the spectrum of its efficacy against sexually transmitted pathogens, and, ideally, increase its flexibility of use. One modification involved covalently bonding an additional chemical entity, Zinc, to the structure of the same carrageenan, PDR98-15, that is used in the manufacture of Carraguard®. This has resulted in a significant improvement in formulation. The new second-generation microbicide, PC-710, has been shown to be significantly more effective in blocking HIV infection *in vitro* and herpes simplex virus type 2 (HSV-2) infection in mice than Carraguard. In addition, PC-710 has proven to be effective in protecting mice from HSV-2 infection for several hours, even when applied post–viral exposure. These attributes of PC-710—increased strength, flexibility of use, and duration of use—warrant moving it into the product development pipeline. Council researchers are proposing to expedite preclinical studies that will establish the basis necessary to achieve US Food and Drug Administration (FDA) approval to begin clinical studies.

A recent award from the National Institute of Child Health and Human Development has provided funding for investigating the potential of the PC-710 formulation and other second-generation microbicides currently being developed in the laboratory. However, this funding is limited to evaluating formulations effective *in vitro* against HIV and *in vivo* against HIV and other sexually transmitted pathogens, evaluating their influence on dendritic cell function in mediating the transmission of HIV, monitoring preliminary stability, and examining the spreading and retention properties of the formulation. In order to advance PC-710 into clinical studies, other funding is needed for preclinical testing.

Final Report:

As was discovered with many other formulations, finding the optimal method for combining ingredients can be quite challenging. In Year 5, it was discovered that the method for formulating PC-710 generated an inconsistent formulation, including an inconsistent concentration of active ingredients. As a result, researchers developed a new method of formulating PC-710, which proved much simpler, as well as producing a consistent formulation. The new formulation re-entered the development pipeline via the laboratory screening and development regimen applied to all new formulations under development, and is described in activity: "CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds" (PC-815).

Several laboratory batches of new PC-710 formulation were stored at 25°C or 40°C for stability testing. Viscosity, pH and zinc content were determined before incubation and every week for four weeks. In some cases zinc content was determined by sampling from the top and bottom of the formulation jar to assess homogeneity. The PC-710 formulations appeared to be stable, homogenous and consistent at 25°C and 40°C at 4 weeks of incubation. The PC-710 formulation performed similarly to its predecessor (the old version

of PC-710) in *in vitro* HIV efficacy assays and in the HSV-2/mouse efficacy system.

PCP funding was critical in early stages of PC-710 development, allowing researchers to explore the finding that zinc bound to carrageenan produced an enhanced formulation that demonstrated efficacy when applied before and after viral challenge in the HSV-2/mouse model. PC-710 also appeared to provide more protection from HIV-1 *in vitro* than did Carraguard. As stated above, the stability of the initial PC-710 formulation was not optimal, prompting researchers to develop an improved formulation, which appears to be stable and effective. Development will continue on PC-710 via other funding sources.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2003 – June 2014

Objective: To assess the suitability of PC-815, a novel combination formulation containing Carraguard® and a non-nucleoside reverse transcriptase inhibitor (NNRTI), for use as a safe, stable, and effective microbicide.

Activity Description:

Medivir Corporation has recently transferred ownership to the Population Council of an anti-HIV drug, MIV-150, for use as a potential microbicide. The compound is a non-nucleoside reverse transcriptase inhibitor (NNRTI) with high specificity for both HIV-1 and HIV-2. Additionally, it exhibits poor bioavailability when administered orally, an attractive property for a microbicide, as it suggests that if placed in the vagina the compound would not be systemically absorbed (and, if absorbed in small amounts, it would not cause systemic adverse events). The Population Council's Microbicides Program has combined MIV-150 with Carraguard to create a formulation called PC-815.

The development of PC-815 has a jump start since Medivir Corporation, in a joint program with Chiron Corporation, has already conducted extensive toxicology and pharmacokinetic testing on MIV-150. Additionally, preliminary experiments at the Population Council have shown that Carraguard does not disrupt the antiviral activity of the new compound, and that Carraguard in fact increases the stability of MIV-150. Results from preliminary *in vitro* experiments indicate that MIV-150 offers protection from infection by both HIV-1 and HIV-2 at concentrations significantly lower than those needed for PDR98-15 carrageenan, the active ingredient in Carraguard. And, when MIV-150 and Carraguard are combined into PC-815, an additive protective effect is observed.

Future research and analysis will focus on testing the safety, toxicology, and pharmacokinetics of vaginally-delivered PC-815. In addition, longer-term stability tests will be initiated, production methodology will be validated, and efficacy will be evaluated in both *in vitro* and *in vivo* assays.

Final Report:

The decision to pursue development of PC-815 stemmed from the encouraging results obtained from initial testing. Combining MIV-150 with Carraguard was shown to produce an additive effect against HIV free virus *in vitro* as compared to Carraguard alone and to result in a product that was nontoxic to vaginal cells and stable for one month. These results indicated that combining the two compounds into PC-815 increased microbicide strength compared to Carraguard alone, without altering the toxicological or stability profile of Carraguard.

A screening and development regimen was designed to systematize the development of this novel combination microbicide. Because PC-815 contains two active ingredients, a wider range of testing had to be performed to ensure that one active compound was not having a deleterious impact on the other active compound. Early testing results from the screening and development regimen showed that PC-815 is effective against the range of subtypes of HIV-1 most commonly transmitted through heterosexual intercourse in the developing world; is active against HIV-1 and HIV-2 both in the presence and in the

absence of seminal fluid; and remains stable for six months. More recently, PC-815 has proven to be nontoxic in a ten-day rabbit vaginal irritation study. Progress is continuing with screening tests that include strength, stability, toxicity, and pharmacokinetics assays which are more extensive and more sensitive than those previously conducted.

Finding the optimal way to combine ingredients is one of the biggest challenges in formulation development. This was particularly an issue with PC-815, since Carraguard is a water-based formulation, and MIV-150 is not soluble in water. To overcome this problem, laboratory researchers have been investigating the use of ethyl alcohol (EtOH) as a solvent for MIV-150, which would make it compatible with incorporation into a water-based formulation.

Because of the extensive toxicology profile of MIV-150, the aim for PC-815 development is to expedite its process through the development pipeline and into clinical trials. Towards this end, a protocol entitled "A Phase I randomized, double blind, crossover safety study of two microbicide formulations: PC-815 and Carraguard" has been approved by the Council's Institutional Review Board (IRB), and an Investigator's Brochure and an Investigational New Drug Application (IND) are being finalized for submission to the U.S. Food and Drug Administration. PC-815 and Carraguard trial gels will be produced at the Center for Biomedical Research. For the large-scale Phase 2 expanded safety trial, technical transfer and scale-up of manufacturing for production of larger amounts of the gels will take place, and the trial formulations will be chemically characterized to establish a chemical profile, which is critical to ensuring batch-to-batch consistency in production and for gaining regulatory approval for the clinical trials.

Research and development are continuing with funding from the Population Council Product Development Cooperative Agreement, and work on this activity is expected to be completed by June 2014.

Implementing Organization(s): Population Council

Collaborating Organization(s): Chiron Corporation
Medivir Corporation

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Blocking DC–Virus Spread with Carrageenan-Based Agents

Part of project Number/s: 08300

Country/ies: United States

Technical Coord.: Melissa Pope

Period: July 2003 – June 2004

Objective: To determine whether carrageenan-based agents can block dendritic cell (DC)-driven immunodeficiency virus transmission *in vitro* and *in vivo*.

Activity Description:

Employing established *in vitro* assays, researchers at the Center for Biomedical Research (CBR) began to evaluate whether carrageenan-based agents block virus capture by DCs as well as whether these agents impede the transmission of virus from DCs to T cells. Recent data had confirmed that the capture of simian immunodeficiency virus by DCs could be efficiently blocked by carrageenan and modified carrageenan without affecting DC viability or membrane phenotype and our *in vitro* assays confirmed and expanded upon this finding. Studies conducted assessed the DC-to-T-cell spread when blocking with Carrageenan and Zn-Carrageenan. Results from these studies provided necessary data to support the *in vivo* studies.

In vivo studies to explore the ability of carrageenans to prevent vaginal infection of rhesus macaques with infectious simian/human immunodeficiency virus experienced an unexpected delay due to animal acquisition and personnel change difficulties. However, preliminary baseline data is being gathered and the *in vivo* studies will continue employing funds from other sources. The plan, slated to start in 2005, is to compare Carraguard® to Zn-Carrageenan utilizing viral load and immune responses assays as a gauge post-virus challenge. All necessary approvals and protocols are in place.

Final Report:

The *in vitro* studies analyzing carrageenan DC-virus biology were finalized within the project year and a manuscript is currently being prepared for submission in 2005. Our assays employed the use of Carageenan and Zn-Carageenan (which was the most promising modified Carageenan compound at the time) as blocking agents in the virus-DC-T cell milieu. Results demonstrated that while both compounds can substantially block the ability of DCs to capture the virus, neither compound had any effect on documented DC biology. Carrageenan and Zn-Carrageenan had no effect on immature and mature DC viability, phenotype, endocytic ability, or antigen presenting capability. For these *in vitro* assays, virus concentrations used were routinely substantially greater than those that would be encountered in a natural setting, therefore our *in vitro* observations suggest that even in the presence of large amounts of virus, Carrageenans are able to impede the DC-virus interactions necessary for virus to bind and be internalized by immature and mature DCs. This is of importance, since in a human microbicide setting, it is crucial that a product exhibit microbicidal efficiency while maintaining the integrity of the immune system at mucosal tissues. Furthermore, these results have allowed for the progression of our focus to move to the new aims proposed in the new USAID agreement involving the *in vitro* characterization of PC-815 in the DC setting.

The *in vivo* arm of the studies planned for this funding period were somewhat delayed but have begun. Difficulties encountered by a personnel change and an unexpected surge in demand for the animals needed to conduct the study precipitated the delay. All animals needed were purchased and baseline data acquisition has begun. The *in vivo* Carageenan studies evaluating Carrageenan and Zn-Carrageenan for their ability to prevent vaginal transmission of SHIV162P are scheduled to begin in 2005. These studies

will continue as originally outlined; however, funds from non-USAID sources will be used to complete these studies. The importance of this study cannot be overlooked and the results of this research will parallel well with the proposed research outlined in the new USAID agreement. Some of the animals from this study are later slated to be used as control groups for the new USAID agreement. Concurrent with these studies, a Pilot Study granted by Tulane National Primate Research Center is currently establishing the HSV vaginal infection model in macaques that will be necessary in the new USAID agreement. Our most recent research on *in vitro* HSV-2-macaque DC biology demonstrated that Indian and Chinese Rhesus macaque DCs exhibit comparable biology and susceptibility to HSV-2 infection. The data from these *in vitro* experiments is being readied in a manuscript for submission in 2004. These data lend support for the successful establishment of the HSV-2 vaginal infection model needed for the continuing macaque studies supported by the new USAID agreement.

Implementing Organization(s): Population Council

Collaborating Organization(s): Tulane National Primate Research Center

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

New Technologies and Strategies for RTI Interventions

Program Summary

Non-HIV reproductive tract infections (RTIs) constitute the second major cause of disease burden (after maternal-related causes) in young adult women in resource poor countries. An estimated 340 million curable sexually transmitted infections (STIs) and 6 million new HIV infections occur annually. Curable STIs such as gonorrhea and chlamydia, when not treated properly, can lead to serious sequelae such as pelvic inflammatory disease and infertility. Furthermore, a broad array of RTIs have been shown to increase susceptibility to HIV and HIV infectiousness. Effectively diagnosing and treating curable sexually transmitted infections, as well as enhancing efforts to prevent new infections, are therefore critical public health endeavors. The Population Council, with support from USAID under the Population Council Program III (PCP3), has made a number of important inroads toward these ends through evaluation of new technologies, including self-sampling techniques for STI sample collection and the use of rapid point-of-care diagnostics. Both new technologies have been explored for home-based versus clinic-based use. Council researchers also have been actively documenting partner notification strategies and prevalence of key infections as well as working to improve reporting of sexual risk behaviors. All of this work has served the dual purpose of generating useful information to improve public health systems and to reduce RTIs, as well as exploring ways to facilitate and enhance HIV/STI prevention clinical trials. Additionally the process of implementing this program of work has been effectively used to increase research capacity among local counterparts.

Self-sampling for reproductive tract infections

Several previous studies have shown that self-collection of vaginal swabs or tampons is a valid way of collecting specimens for diagnosis of a variety of reproductive tract infections. Self-sampling techniques may significantly aid in efforts to reach underserved populations that need improved diagnosis and treatment, particularly populations with elevated prevalence of asymptomatic RTI. Additionally, such self-collection is a potentially useful tool in field trials for HIV/STI prevention, in which women are asked to undergo frequent testing for RTIs. Until now, these self-collection techniques had not been adequately tested in resource-poor settings, and had not been used to diagnose multiple pathogens.

In preparation for the large-scale trial of the Council's lead candidate microbicide Carraguard®, the Population Council, in collaboration with the University of Cape Town (UCT), implemented a study in Gugulethu, South Africa to test the feasibility, validity, and acceptability of self-sampling techniques. Self-sampling with both tampons and swabs resulted in satisfactory validity for gonorrhea, chlamydia, bacterial vaginosis, and yeasts, and with swabs only for high-risk human papillomavirus types, though not for trichomoniasis, diagnosed by culture. Both self-sampling methods were found to be feasible and as acceptable as speculum examination. Researchers concluded that self-sampling should be further explored for RTI screening strategies in resource poor settings, as well as for use within HIV/STI prevention trials.

A second study, also in collaboration with UCT, was undertaken in Gugulethu to explore the use of self-sampling at home. Simultaneously, a sister study was implemented in Brazil, in collaboration with the Centro de Estudos Augusto Leopoldo Ayrosa Galvão Research Center (CEALAG). Preliminary results from both studies found that women generally found self-sampling to be acceptable and easy, either at the clinic or at home. The studies showed that home-based self-sampling for RTIs was acceptable and feasible and should be further explored as an option within these communities.

Rapid point-of-care testing

The World Health Organization recommends syndromic management of STIs in areas where laboratory diagnosis is not feasible due to costs and/or available technology. However, syndromic management of infections often fails to diagnose asymptomatic clients, especially among women, who have been demonstrated to make up as much as 50% of STI cases. Additionally, syndromic management often results in over-treatment of clients, notably women diagnosed with "abnormal discharge."

Rapid point-of-care testing, where specimens are collected and tested in a short time, is a potentially effective method for improving diagnostic validity at a lower cost than current gold standard laboratory tests, while still providing same-day treatment, as syndromic management. As part of the studies in Brazil and South Africa to explore home sampling, introduction of a rapid Optical Immunoassay test for gonorrhea and chlamydia in a clinic setting, as well as an easy-to-administer litmus-type test for trichomoniasis for use at home and at the clinic was tested for feasibility. Preliminary results from both studies found that it was feasible and acceptable for both women and providers to use rapid tests in both clinic and home settings, although they also suggest that the OIA CT and GC tests, which require significant time and training, did not perform very well.

Home-based versus clinic-based RTI screening

Studies suggest that home-based screening may encourage RTI testing and treatment among young people, by virtue of convenience, privacy and avoiding the stigma of clinic attendance. A second generation of studies tested the hypothesis that home-based screening would increase the number of women screened for RTIs in Brazil and South Africa. Preliminary results from both studies suggest that slightly more women responded to the home-based initiative than clinic-based screening, although this difference was not statistically significant. While home-based screening is a viable alternative to clinic-based screening, additional efforts are needed to attain improved compliance with screening initiatives.

Partner notification strategies

Effectively treating a woman for an STI without treating her partner(s) often leads to re-infection. Partner notification and treatment is an essential component of STI care, but is often difficult to implement effectively. In the second generation of self-sampling studies, we explored the use of patient-delivered medication (in which a woman with an infection brought the treatment to her partner[s]). It was found that introducing this option was a viable option in both study locations and resulted in a high proportion of partners being treated. Brazilian and South African collaborators on this study plan to publish these findings with commentary in local medical journals to begin the process of strengthening their respective health ministries' guidelines on partner notification and treatment.

Prevalence of infections

This body of work provided important data on the prevalence of the sexually-transmitted infections bacterial vaginosis, yeasts, trichomoniasis, Chlamydia, gohorrhea, and human papillomavirus (HPV) in the study communities. An alarmingly high rate of high-risk human papillomavirus (HPV) was found in Gugulethu, South Africa (36%), and analysis of the types of HPV found on self-obtained vaginal swabs versus clinician-obtained endocervical swabs is being performed in late 2005. Prevalence data from this study was used as background information for the Phase 3 trial of Carraguard undertaken in the same community. In Brazil, stored specimens were tested and typed for HPV, as little is known about the prevalence of specific HPV types in this community. Additionally, these specimens were tested for *mycoplasma genitalium*, for which little to no data currently exists in Brazil. These results will be available in late 2005.

Improving reporting of sensitive behaviors

Understanding the relationship between sexual behavior and the prevalence of STIs and HIV is imperative for designing effective interventions that maximize STI/HIV prevention and minimize re-infection. If risky sexual practices and partnering are under-reported in face-to-face interviews, or if condom use is exaggerated, the ability to design and evaluate interventions to prevent STIs/HIV is greatly hindered. Additionally, accurate reporting of these types of behaviors in the context of an HIV/STI prevention trial is critical to being able to interpret trial results.

As part of the Council's work to improve reporting and documentation of sensitive sexual behaviors (further reported in the summary for the program "Understanding and Meeting the Needs of Adolescents"), a randomized sub-study to look at the use of audio computer-assisted self-interviewing (ACASI) compared with face-to-face interviewing was included in the Brazil study, with the added benefit of having biological markers of STI infections to act as external validation for any differentials found in reporting. Preliminary results from the study indicate higher rates of reporting of almost all sensitive behaviors in the ACASI arm. The converse was also true in that socially acceptable or "positive" behaviors, such as having previously had a pelvic exam, had higher levels of reporting in the face-to-face arm. Analysis comparing interview methods in predictive models of sexually transmitted infections has yet to be completed, as has the analysis of the consistency of reporting between two points in time. Nevertheless, the initial results are promising and suggest that the greater confidentiality and privacy afforded by ACASI lead to greater reporting of sensitive behaviors than traditional modes of interviewing.

Capacity building

To sustain and promote changes in health systems requires strengthening in-country capacity for relevant research and advocacy. As such, Council staff have actively and successfully sought opportunities for capacity building during the implementation of this program.

In South Africa, a researcher from the University of Cape Town, with additional support from the Gates Foundation, participated in the University of San Francisco's Center for AIDS Prevention Studies (CAPS) Program, in which she developed the protocol for the home-based versus clinic-based screening study in South Africa with joint mentoring from Council staff. For this study, UCT staff took the lead in designing the questionnaires, with technical assistance and feedback from Council staff. Additionally, UCT staff expressed an interest in taking over the data management function for the second study and were therefore trained and implemented data management successfully for this study. This study also functioned as a "trial run" for the new study facility, which was built for the larger Phase 3 Carraguard study.

The Brazil study was the first international collaboration for the local partner organization. Staff were trained in designing and administrating budgets for subawards, maintaining good clinical practices, and designing and upholding standard operating procedures. These collaborators are now actively seeking to establish a research group in São Paulo and are writing proposals for new projects. Additionally, members of the staff were trained in the technical aspects of the computer interviewing software program during the design of the baseline questionnaire, and were then able to tailor the program themselves to administer the follow-up questionnaire, enabling them to use the ACASI method again in any new studies they design.

In both studies, since no commercial kits are currently available for trichomoniasis polymerase chain reaction (PCR), local laboratories calibrated and designed in-house PCR capability for trichomoniasis. Our

collaborator in Brazil has since offered the use of this low-cost test to staff within his hospital more broadly. Additionally, in Brazil, lab staff received training in the use of the Roche COBAS Amplicor system for diagnosis of gonorrhea and chlamydia, although the renting of this equipment was not sustainable after the study ended.

Finally, staff from both UCT and CEALAG attended and presented at a number of local and international conferences and meetings, including the International Society for Sexually Transmitted Diseases Research meetings (ISSTDR) in 2003 and 2005, Microbicides 2004, the South African AIDS Conference, the International Conference on Chemotherapy, the 6th Brazilian Epidemiology Conference, and an in-house investigators meeting in New York.

Dissemination activities

In addition to dissemination by local partner staff, results were also disseminated at an Alliance for Microbicide Development Meeting in Washington, DC in January 2005; "Hormonal Contraception and HIV Transmission: Links? Mechanisms? Implications," at Gynuity Health Projects, New York Academy of Sciences, May 2005; the International Center for AIDS Care and Treatment, Columbia University; and will be disseminated at the American Public Health Association meeting later this year. Additionally an abstract has been submitted to the Population Association of America. A publication on the feasibility, acceptability, and validity of self-sampling in South Africa is currently under review by a journal, and additional articles are anticipated to be submitted in the next few months. The Brazil team is organizing a meeting with local stakeholders in early 2006 to disseminate the many findings from this study, and are writing publications to be submitted to Brazilian peer-reviewed medical journals. The South African team is currently focusing on disseminating the findings on partner-delivered medications to key officials.

In conclusion, Council staff and their collaborators in South Africa and Brazil, through USAID's generous support of the program New Technologies and Strategies for RTI Interventions, have made significant contributions to research and programs aimed at reducing RTIs, including HIV, worldwide.

Reproductive Tract Infection Sampling Study

Project Number/s: **05605**
Country/ies: South Africa
Technical Coord.: Heidi Jones
Period: September 2001 – March 2004
Objective: To assess self-sampling procedures (tampons and vaginal swabs) for reproductive tract infections (RTIs) in a clinic setting and to determine the prevalence of human papillomavirus (HPV) subtypes to inform the Phase 3 Carraguard® Efficacy Trial.

Activity Description:

A study will be conducted in Gugulethu, South Africa, to assess the performance, acceptability, and feasibility of new methods of collecting samples for RTI testing that may be more convenient and less invasive than standard sampling carried out during a speculum-aided pelvic examination. Recently developed sampling techniques include tampons and vaginal swabs that can be used by women themselves and do not require a pelvic exam. However, these new techniques have not yet been adequately tested in developing-country settings. In this study, researchers will compare the performance of the new sampling methods to that of the "gold-standard" clinician-obtained samples. The study will also allow measurement of the prevalence of various subtypes of HPV in Gugulethu. HPV will be one of the study endpoints in the Phase 3 trial of Carraguard, however, no data are currently available on HPV prevalence in the South African trial communities.

Final Report:

In Year Five, an oral presentation on the main study findings and one on the Human Papillomavirus (HPV) findings were presented at the International Society of Sexually Transmitted Diseases Research (ISSTDR) Congress in Ottawa, Canada in July 2003. Additionally, a poster presentation on syndromic management was presented at ISSTDR. In March 2004, two poster presentations, one on acceptability and one on the main study findings, were presented at the Microbicides 2004 Conference in London. Coding of qualitative transcripts was completed using Atlas-ti software. Additionally, brown bag presentations were given at the Population Council's New York, Washington, D.C. and Johannesburg offices for internal dissemination of study results. Manuscript preparation to peer-reviewed journals is ongoing.

In this study, 450 women were recruited from a community health center in Gugulethu, South Africa from January to July, 2002, of whom 150 women came in with reproductive tract infection complaints and 300 came for other reasons, such as family planning or maternal & child health. Women from both groups were randomized to receive either a tampon or two swabs. All women took their own vaginal specimen using either the tampon or swabs, as well as underwent a pelvic exam in which a clinician took swabs. Results from the laboratory diagnosis of gonorrhea, chlamydia, trichomoniasis, human papillomavirus, yeasts, and bacterial vaginosis using the self-obtained specimens were compared to results using the same laboratory diagnostics on clinician-obtained samples.

The prevalence of HPV was high, with 36% of the women positive for a high-risk type of HPV (using the Digene Hyrbrid Capture II test). The prevalence for chlamydia was 11%, gonorrhea 7%, trichomoniasis 11%, bacterial vaginosis (both symptomatic and asymptomatic combined) 62% and yeasts 28%.

Concordance was high between the self-samples and the clinician-obtained samples for gonorrhea, chlamydia, yeasts and bacterial vaginosis, ranging from 93–96 percent concordance with a kappa ranging

from 0.78 to 0.86. However, self-sampled specimens did not compare favorably with clinician-obtained specimens for the diagnosis of trichomoniasis and HPV, most likely due to the way these specimens were processed. Both self-sampling methods were found to be feasible, and as acceptable as speculum examination. Younger women tended to prefer self-sampling to the pelvic exam.

The results demonstrated that the self-sampled specimens performed favorably against the gold standard with the exception of two infections—trichomoniasis and HPV—and should be considered viable alternatives for collecting specimens in future studies. Using self-sampling methods may help decrease barriers to RTI screening for younger women who tended to prefer self-sampling over a pelvic exam. However, if self-sampling is to be used for trichomoniasis, diagnostic testing of the specimen using culture in Diamonds Medium cannot be recommended, a NAATS test should be used. If self-sampling for HPV is to be used, the use of a tampon in phosphate buffered saline cannot be recommended. A swab should be used and placed in HPV-specific transport medium.

Implementing Organization(s): University of Cape Town (I01.81A)
Population Council

Collaborating Organization(s): Medical University of Southern Africa

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

Home Sampling and Rapid Testing for Reproductive Tract Infections

Project Number/s: **05608**
Country/ies: Brazil, South Africa
Technical Coord.: Heidi Jones
Period: July 2002 – August 2005
Objective: To assess the performance, feasibility, and acceptability of home-based and clinic-based self-sampling by women in developing countries for reproductive tract infections (RTIs); and to field-test new rapid diagnostic tests for RTIs in home and clinic settings.

Activity Description:

In many countries women do not have access to adequate health services for the diagnosis and treatment of RTIs. Even when services are available, diagnosis of RTIs typically requires a clinician to take swabs during speculum-aided pelvic exams, which are invasive and often pose a disincentive for seeking care. Home-based self-sampling and rapid testing may significantly help in reaching underserved populations in need of improved RTI diagnosis and treatment (particularly in populations with elevated prevalence of asymptomatic RTIs), and may also contribute to reducing HIV transmission by improving RTI detection and treatment. The completed activities were conducted as a follow-up to a study conducted in collaboration with the University of Cape Town, which was funded under the PCP3 activity "Reproductive Tract Infection Sampling Study" (project #05605). In that study, the performance, feasibility, and acceptability of clinic-based self-sampling, using swabs and tampons, was determined by comparing self-sampling with "gold-standard" clinician sampling during a speculum-aided pelvic exam. In this activity, RTI self-sampling at home and at the clinic was assessed in two randomized studies, one each in South Africa and Brazil, to determine if home-based self-sampling was feasible and acceptable and if it was preferable to clinic-based sampling; and new rapid point-of-care diagnostic tests for RTIs were field-tested in both home and clinic settings.

Final Report:

South Africa: Between July 2002 and September 2003, we developed the study protocol, questionnaires and standard operating procedures, and trained study staff. Between September 2003 and March 2004, 626 women aged 14 to 25 were recruited and enrolled in Gugulethu, Cape Town. Three hundred and twelve women were randomized to receive a home-based RTI screening kit for chlamydia, gonorrhea, and trichomoniasis, and 314 women were given a clinic appointment to self-sample for these same RTIs. The home kits consisted of swabs for self-sampling, a rapid trichomoniasis dipstick test, instructions, a self-administered questionnaire (SAQ), and a prepaid package to send specimens to a central laboratory for testing. Both groups completed the SAQ after RTI sampling and had a 6-week follow-up interview. Data collection was completed in August 2004, with 568 (91%) of the women completing their follow-up visit.

Preliminary data indicate that 47% of women in the home group returned their kits in the mail, compared to 42% in the clinic group who kept their appointment ($p=0.49$). The prevalence of RTIs using polymerase chain reaction (PCR) tests was: 17% home group vs. 27% clinic group for chlamydia ($p=0.08$); 9% home group vs. 11% clinic group for trichomoniasis ($p=0.51$); and 8% in both groups for gonorrhea. Of those who completed the SAQ, 77% in the home group vs. 84% in the clinic group found the experience acceptable ($p=0.64$). At follow-up, reasons cited for preferring to sample at the clinic included the fear of making mistakes and no or too little privacy at home. Of those in the home group who returned their kits, 90% reported being able to successfully follow the instructions for taking and mailing their samples.

Brazil: Between April and November 2004, 818 women aged 18 to 40 from a low-income neighborhood in São Paulo, Brazil were enrolled in the second study. Data collection was completed in February 2005, with 768 women (94%) completing their 6-week follow-up visit. The study design was similar to that for South Africa except that, in the clinic group, the clinician took a sample in addition to the clinician-monitored self-sample, and, in the home group, the women were asked to drop off the used kits at the clinic rather than send them by mail.

Preliminary data indicate that a slightly higher proportion of home group participants (93%) returned samples before the 6-week visit than clinic group participants who kept their appointments (90%; p=0.06). Nine percent of the women tested positive for chlamydia, 3% for trichomoniasis, and 2% for gonorrhea (for gonorrhea, stored samples have been retested to confirm this result since it is higher than has been previously found in Brazil; results are not yet available). The testing of stored specimens for mycoplasma genitalium and HPV types has recently been completed, with results anticipated shortly. The majority of women reported that they would perform self-sampling again (98%), rated self-sampling as easy (97%), and, in the home group, had successfully collected specimens (97%). Collection procedure preferences were influenced by randomization group: the home group preferred self-sampling at home, while the clinic group preferred sampling by a clinician. In both groups, future preference for self-sampling at home was significantly related to having completed high school and previous use of tampons ($p<0.05$), and future preference for self-sampling in general was significantly associated with more schooling ($p<0.05$).

Self-collection of vaginal swabs at home in both South Africa and Brazil was feasible and acceptable, and could be a useful strategy in future RTI screening programs and clinical trials. These studies suggest that women are as likely to comply with a home-based screening program as a clinic-based program, and that, in future programs, women may even be more likely to comply with a home-based program when the venue's standard of care is more representative of community clinics than were our study sites (our sites — a teaching clinic in Brazil and a clinical trial site in South Africa — have unusually high quality of care standards). Home-sampling did not result in an increase or decrease of the number of infections detected.

The study design for the Brazil study was presented at the 6th Brazilian Epidemiology Conference in July 2004. In April 2005, we held an investigators meeting in New York with two Gates-funded projects which had used rapid syphilis tests in antenatal care settings. In July 2005, we presented results from the South Africa and Brazil studies at the International Society for Sexually Transmitted Disease Research (ISSTDR) meeting in Amsterdam, and shared the results with clinic staff in South Africa. A dissemination meeting will take place in Brazil in early 2006, and three articles will be submitted to peer-reviewed journals.

Implementing Organization(s): Centro de Estudos Augusto Leopoldo Ayrosa Galvao Research Center (CEALAG) (I03.42A)
University of Cape Town (I03.31A)
Population Council

Collaborating Organization(s): Gynuity
International Antiviral Therapy Evaluation Center

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

Audio Computer-Assisted Self-Interviewing (Audio-CASI) to Assess Reporting of Sensitive Behaviors

Project Number/s: **05609**
Country/ies: Brazil
Technical Coord.: Barbara Mensch, Heidi Jones
Period: May 2003 – August 2005
Objective: To assess the feasibility and acceptability of audio-CASI (ACASI) in a clinic setting compared with face-to-face interviewing; to determine whether ACASI produces significantly higher levels of reporting of sensitive behaviors; and to evaluate whether ACASI results in a greater association between reporting of risk-behaviors and sexually transmitted infections (STIs) than face-to-face interviewing.

Activity Description:

Understanding the relationship between sexual behavior and the prevalence of STIs, including HIV, is imperative to designing effective interventions that maximize STI/HIV prevention and minimize re-infection. If risky sexual practices and partnering are under-reported in face-to-face interviews, or if condom use is exaggerated, the ability to predict STI infection/re-infection from reported behavior will be hindered. This study provides an opportunity to examine the associations between the reporting of risky sexual behaviors and the presence of biological markers of infection by interview method.

As part of an experimental study evaluating home-based versus clinic-based screening for and diagnosis of STIs in São Paulo, Brazil, a total of 818 women were randomized at enrollment to either face-to-face or ACASI interviews and were asked a series of questions concerning their sexual behavior and practices. At a 6-week follow-up visit, all women were interviewed using ACASI. Comparing the reporting of behavior between interview methods at baseline, changes in reporting between baseline and 6-weeks, and associations of reporting of risky behaviors with STI infection will provide valuable information on the collection of sexual behavior data and will influence future STI/HIV intervention studies.

This activity is a collaboration between IPD and PRD staff.

Final Report:

We completed a randomized study comparing ACASI and face-to-face interviews as part of a larger study on home-based versus clinic-based screening for STIs in Brazil, funded under the PCP3 activity "Home Sampling and Rapid Testing for Reproductive Tract Infections" (project #05608).

From May to December 2003, we developed the protocol, instruments, and standard operating procedures. In December 2003, the ACASI program, designed by Population Council staff using Microsoft Visual Basic and Access, was pre-tested. The results of pre-testing led to an adjustment in how fast the questions were read and to the decision to allow respondents to return to the previous question. Local staff at the study clinic were trained on the technical details of the ACASI program during the pre-testing so that they would then be able to independently modify the program for the 6-week interview questionnaire, which they did with the inclusion of additional questions on the acceptability of STI screening procedures in the 6-week interview questionnaire.

Between April and November 2004, 818 women aged 18 to 40 from a low-income neighborhood in São Paulo, Brazil were enrolled in the study. Women were randomized at enrollment to an ACASI or face-to-

face interview, and then were all interviewed using ACASI at the 6-week follow-up visit. Data collection was completed in February 2005, with 768 women (94%) completing the 6-week follow-up visit.

Preliminary study results indicate higher rates of reporting of most sensitive sexual behaviors in the ACASI arm. Thirty-three percent of ACASI respondents reported practicing anal sex in the last 6 months compared to 23% in the face-to-face arm ($p < .01$). Similarly, 66% of ACASI respondents reported oral sex in the last 6 months versus 53% face-to-face ($p < .01$), and 8% reported having ever exchanged sex for drugs, money or favors, compared to 3% in face-to-face ($p < .001$). Reporting of intimate violence was also higher in the ACASI group (18% vs. 16%), although the difference was not statistically significant. The converse was also true; there were higher rates of reporting of 'positive' behaviors in the face-to-face arm. For example, 94% of women in the face-to-face arm reported having ever had a pelvic exam, versus 82% in the ACASI arm ($p < .01$). Ninety-six percent of the women enrolled in the study were tested for STIs, and 13% were positive for trichomonas, gonorrhea and/or chlamydia. Analysis comparing the differences in reporting and associations with STIs and analysis of the consistency of reporting between enrollment and the 6-week follow-up have yet to be completed. An initial look at consistency suggests that both groups had similar inconsistencies over time, that is, a similar proportion of women changed their responses from higher-risk to lesser-risk behaviors and vice versa in each group. Further analysis is needed to interpret these findings. Nevertheless, the initial results are promising and suggest that the greater confidentiality and privacy afforded by ACASI lead to greater reporting of sensitive behaviors than traditional modes of interviewing.

An initial description of the study design was presented at the 6th Brazilian Epidemiology Conference in July 2004. Since then, preliminary results from this study have been presented at: an Alliance for Microbicide Development meeting in Washington, DC in January 2005; a Gynuity Health Projects conference at the New York Academy of Sciences in May 2005; the International Center for AIDS Care and Treatment at Columbia University in June 2005; and the International Society for Sexually Transmitted Diseases Research (ISSTDR) meeting in Amsterdam in July 2005. Additionally, a discussion of these results was included in a larger investigators meeting on home-based versus clinic-based screening initiatives and the use of rapid diagnostics in New York in April 2005. Results will be presented at the upcoming Annual Public Health Association Meeting in Philadelphia in December 2005, and an abstract has been submitted for the 2006 Population Association of America Meeting. Finally, a dissemination meeting at the study site is anticipated to take place early in 2006, and two to three articles will be submitted to peer-reviewed journals.

Implementing Organization(s): Centro de Estudos Augusto Leopoldo Ayrosa Galvao Research Center (CEALAG) (I03.42A)
Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 2.1

Expanding Contraceptive Choice & ECC-related Mission-Funded Initiatives

Program Summary

The Population Council's Expanding Contraceptive Choice (ECC) program worked to improve the reproductive health of women and men in developing countries by expanding their contraceptive choices and their options for preventing sexually transmitted infections (STIs), including HIV infection. The program aimed to increase the availability, accessibility, and use of safe, effective, and acceptable contraceptive and dual-protection technologies (methods that prevent both pregnancy and STIs); and it sought to introduce (or reintroduce) these technologies in ways that were programmatically feasible and sustainable and were consistent with individuals' reproductive health goals. ECC staff worked with women's advocacy and health groups at community, regional, and national levels to increase individuals' informed choices within both health care and alternative service delivery systems. The program was guided by WHO's Strategic Approach to Contraceptive Introduction, a three-stage strategy designed to help policymakers and health professionals address the complex issues surrounding the introduction of contraceptive methods, including client preferences, service delivery system capabilities, provider competence, and sustainability.

The ECC program was staffed by a director in New York, and technical staff in each of three regions: in Nairobi and Lusaka for the East and Southern Africa region, in Dakar for the West and Central Africa Region, and in Sao Paulo for the Latin America and the Caribbean region.

USAID supported the ECC program with a mix of core and field support funds through Year Three of the Population Council Program III, with funded projects persisting to completion. Several projects in Zambia and Brazil that were begun under the ECC program but required renewed funding were sustained forward by the USAID missions. USAID/Zambia and USAID/Brazil also initiated new projects in collaboration with their regional Council colleagues during Years Four through Six, funded entirely by field support.

This section includes all projects completed either under the ECC program, or under subsequent mission-funded initiatives that arose from the working relationship between the USAID mission and former ECC regional Council staff. It is divided into three sections, one for each region's body of work under the PCP3.

East and Southern Africa Region

Regional Summary

Work under the Population Council Program III (PCP3) in East and Southern Africa began as part of the Council's Expanding Contraceptive Choice (ECC) program, supported by a combination of core and field support funds. After USAID/Washington discontinued funding for the ECC program, activities in the region nevertheless continued: The strong working relationship between regional Population Council staff and the USAID mission in Zambia allowed for the fruition of the major "From Pilots to Regional Program" (PRP) project, and two new research projects, on dual protection and on emergency contraception.

The major achievements in the region during the six years of funding through the PCP3 cooperative agreement are summarized below.

Formulated and field tested a sustainable, cost-effective model for scaling up health care interventions originally introduced on a pilot basis.

The last ten years have seen a concerted effort by the development community to identify the successes of past health interventions, heighten awareness of them, and maximize their impact through some form of replication or scaling-up. While each step in this process has generated unique sets of problems and challenges, it is the last that has been particularly problematic, in large part because so few models exist to guide and inform the scaling-up process in any systematic manner. The PRP project has contributed significantly to filling this critical gap.

Born out of the need to expand a series of successful pilot interventions in Zambia's Copperbelt Province, the PRP Initiative developed into a flexible, innovative, and sustainable framework to guide the scaling-up of pilot interventions generally. Designed around a series of logical stages and conceptual objectives, the model applies a systematic approach for recognizing and responding to the tensions inherent in any scaling-up effort. These include conflicts between quality and quantity; expansion and local relevance; and higher costs and increased benefits.

In the past three years, the PRP Initiative has successfully increased both contraceptive choice and prevalence; it has introduced innovative, cost-effective strategies to train health care providers; and it has forged new linkages between the health sector and the communities it serves. But perhaps even more importantly, it has set in motion a scaling-up process that promises to endure well beyond the end of USAID funding. In 2004, the Zambia Ministry of Health selected the PRP framework as its model, or best practice, for scaling up reproductive health services over the coming decade. Already joint efforts are underway by the Population Council and Ministry of Health (with WHO funding) to document lessons learned, disseminate best practices nationally, and develop a proposal for submission to key bilateral and multilateral donors. Meanwhile, at the local level, the Copperbelt Provincial Health Office (PHO) has already taken over responsibility for sustaining the scaling-up of its own PRP-inspired interventions. Using resources from its existing budget allocations, the PHO is supporting key district staff to sustain key initiatives in the areas of broad method choice, provider training, and joint-district planning.

Demonstrated how the introduction of new contraceptive technologies can strengthen the quality of reproductive health (RH) services generally.

Though the impetus for introducing any new technology typically derives from some property of the technology itself — its utility, effectiveness, or responsiveness to client needs — our work under the PCP3 has shown how the introductory process can serve as a valuable tool for bringing about changes in the content and quality of RH programs and services. Because technology transfer impacts on virtually every aspect of the service delivery system, the introductory process serves as an effective tool for setting in motion a host of service-related changes. In East Africa, for example, efforts to expand contraceptive choice have been pivotal in simultaneously reinforcing provider skills and knowledge, strengthening supply and logistics systems, and empowering clients to assume a greater role in decision making towards both their health care system and fertility regulation. Nowhere has this "ripple effect" been more evident than in Zambia, where the PRP Initiative brought about fundamental changes in the service delivery system. And more recently, the Council's work to re-introduce emergency contraception (EC) in Zambia's Copperbelt has shown how contraceptive introduction can serve as a conduit for strengthening a whole host of support services (law enforcement, medical, psychosocial and legal) for victims of rape and sexual violence.

In Ethiopia, efforts to introduce EC served as a catalyst for broad-based changes at the service delivery level. It prompted our partner, the local International Planned Parenthood Federation affiliate Family Guidance Association of Ethiopia, to review its policies and procedures over the selection and use of peer providers. Other changes were the introduction of new approaches to disseminate information about young people's RH needs; a heightened awareness of the importance of dual protection and condom use, reinforced through new messages and counseling linking EC and condom use; and the introduction of new service delivery systems designed to track dual protection at the community and service delivery level.

Established the technical expertise and professional credibility required to found *ECafrique*, the Africa Forum on Emergency Contraception.

In 2003, the Nairobi office of the Population Council established a bilingual, international network of health care professionals seeking to mainstream quality emergency contraception services in Africa. Called *ECafrique*, the network is today a respected, independent force for building the knowledge base and institutional framework needed to introduce, deliver, and mainstream quality emergency contraception services.

Though the immediate catalyst for *ECafrique* was grants from the Hewlett and Compton Foundations, the network itself would not have been possible without the legacy of EC-related research carried out under the PCP3. Our USAID-funded work in Zambia, for example, is noteworthy for having pioneered the study of advance provision of EC pills; of the challenges of transitioning from the Yuzpe to a progestin-only regimen; and of the obstacles to introducing EC into both public and private settings. Through the support of the PCP3, the Population Council and Ethiopia's IPPF affiliate were the first in Africa to systematically repackage combined oral contraceptives for emergency use, and to package EC with the male condom. Worldwide recognition of this work played a pivotal role in garnering the support of partner organizations internationally, including in well over three-quarters of all countries in sub-Saharan Africa. It has also made *ECafrique* a credible entity in the eyes of the international donor community. Today, many of the interventions initially begun as pilot studies under the PCP3 are being scaled up with non-USAID funding, either through *ECafrique* or directly to implementing organizations.
contraceptive method mix.

Made possible the re-introduction of DMPA and natural family planning into Zambia's national contraceptive method mix.

Though the process of contraceptive introduction can often strengthen service delivery systems in ways that extend far beyond the immediate properties of the contraceptive technology itself, there are many instances where the significance of introductory efforts does hinge on the ability of that technology to address the distinctive contraceptive needs of key population groups. In Zambia, two such technologies fell into this category: injectable contraception, specifically DMPA, and natural family planning (NFP), particularly the standard days method (SDM).

Though profoundly different in many respects, the status of these methods within Zambia's contraceptive method mix was, five years ago, quite comparable. Opposition towards DMPA, though initially motivated by political and historic concerns, was entrenched among senior staff in the Ministry of Health. As a result, despite considerable demand for the method among users and providers, it remained virtually nonexistent in the public sector. In the case of natural family planning, opposition came from the other end of the spectrum, from lower-level health care providers encouraged to believe that provision of NFP was too complex. In both instances, resistance to these methods meant that the contraceptive needs of a huge sector of the population, particularly the nearly 60 percent of the country who live in rural areas, were not being met.

One of the greatest achievements of the PRP Initiative was to have brought down the many barriers that had, for years, prevented any mainstreaming of injectable contraception and NFP. Through a combination of evidence-based data, innovative efforts at service provision, and sheer persistence, the Council's work under the PCP3 and the preceding PCP cooperative agreement succeeded in bringing about a complete reversal of attitudes towards the two methods. Thanks to the support of USAID and the active involvement of the Copperbelt Provincial Health Office, the year 2005 brought to a close a process that had begun in the mid-1990s, with the launch of a pilot study under the previous PCP Agreement co-funded by WHO. In this year DMPA received regulatory approval by Zambia's Pharmacy and Poisons Board, and SDM was incorporated within the national RH guidelines. In the eyes of the Ministry of Health, the USAID mission, and the RH community generally, credit for incorporation of these methods in the national contraceptive method mix rested squarely with the PRP Initiative and its preceding pilot study.

Partial Support for Population Council Regional Workshop on Implant Technology: Past Experiences and Perspectives for Africa

Project Number/s: **03258**
Country/ies: East and Southern Africa Region
Technical Coord.: John Skibiak
Period: August 2001 – September 2001
Objective: To provide institutional support to an African regional workshop on contraceptive implant technologies.

Final Report:

In June 2001, WHO sponsored an International Consultation on Implantable Contraceptives for Women. Although the Consultation assembled experts from around the world, most came from countries where implant technologies were most widely used. Issues of specific relevance to Africa did not figure prominently, nor were provisions made to ensure that program planners in Africa could make timely use of knowledge gained through experience with contraceptive implants elsewhere.

For these reasons, the Population Council and the Ethiopia Ministry of Health, in collaboration with Schering Pharmaceuticals and Organon, convened a regional conference on contraceptive implant technologies, held in August 2001 in Addis Ababa, Ethiopia. The purpose of this event was to provide an update on new implant technologies, share past experiences with Norplant®, and formulate strategies to improve the quality of future implant services. Approximately 60 individuals from 18 African countries were invited to the conference. Participants included heads of family planning units and regulatory bodies; individuals who manage or are otherwise involved in the introduction of implant technologies; and representatives from cooperating agencies, donor institutions, and implant manufacturers.

The conference began on August 30 with an overview of the WHO Consultation and a summary of key findings from the recently concluded Post-Marketing Surveillance of Norplant® Contraception conference in Addis Ababa, sponsored by the Council's Expanding Contraceptive Choice (ECC) project. Following the three-stage structure of WHO's Contraceptive Strategic Assessment Framework, presenters addressed issues related to implant technologies, service-delivery systems, user needs, and the interfaces among these issues. Presentations on the development and use characteristics of Norplant, Jadelle®, and Implanon® were followed by a discussion of issues related to service delivery and user needs. Among the topics addressed were cost and procurement of new technologies; the role of donor agencies and national regulatory policies in the importation of implants; and the quality and supervision of implant services. On the second day of the conference, discussion focused on user perspectives and lessons learned during the decade-and-a half of contraceptive implant use in Africa. A panel discussion among representatives of key Norplant-providing countries (Ghana, Kenya, Nigeria, and Zimbabwe) focused on the opportunities and challenges associated with sustained delivery of contraceptive implants. Following this panel, presenters addressed the social and cultural acceptability of implants and the need to supplement implants with protection against transmission of sexually transmitted infections, including HIV infection.

The success of this conference was a testament to the generosity and collaboration of international donors, the pharmaceutical industry, collaborating agencies, and the reproductive health community as a whole. The interest generated by the conference was soon evident: as early as November 2001, participants began requesting support to expand implant services throughout the region. Researchers across Africa have

sought information on the new technologies, have asked to participate in studies of contraceptive technology transition, and have shared the lessons of Addis Ababa with their colleagues at home.

Conference proceedings are being prepared for publication.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ethiopia Ministry of Health
Organon
Schering Pharmaceuticals

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Institutional Support for Regional Professional Societies: Support for the East, Central, and Southern African Obstetrical and Gynecological Society Fourth International Scientific Conference

Project Number/s: **03261**
Country/ies: East and Southern Africa Region
Technical Coord.: John P. Skibiak
Period: November 2001 – January 2002
Objective: To provide institutional support for the ECSAOGS conference as part of capacity-building efforts.

Activity Description:

The Population Council's Expanding Contraceptive Choice (ECC) program had a longstanding involvement with regional professional societies—providing them with technical assistance, conducting trainings and workshops, and collaborating on research studies and interventions. Included among these organizations were the Society of Women Against AIDS in Africa; the Latin American Association of Researchers in Human Reproduction; and the East, Central, and South African Association of Obstetrical and Gynaecological Societies (ECSAOGS). As part of efforts to promote cooperation between the international and local family planning and reproductive health communities, and to promote capacity building of local institutions, ECC provided support for a series of seminars and international meetings held by these organizations during Years Two and Three of the Population Council Program III. This activity provided support to the Ethiopian Society of Obstetricians and Gynecologists (ESOG) for hosting the 2001 ECSAOGS conference.

Final Report:

ECC program staff provided support to the Ethiopian Society of Obstetricians and Gynecologists to help fund conference planning and logistics for the annual conference of East, Central, and South African Obstetrical and Gynaecological Societies, held in Addis Ababa, Ethiopia, in November 2001. The ECC medical consultant in Ethiopia gave a presentation at the conference on the evaluation of Ethiopia's national Norplant® program, a project on which ECC staff provided technical assistance (see "Technical Assistance to Evaluation of the National Norplant® Program of Ethiopia"). The conference attracted international organizations, including the International Federation of Gynecology and Obstetrics, the Swedish International Development Cooperation Agency, the United Nations Population Fund, and the World Health Organization, as well as the Council; local nongovernmental organizations; representatives of the African reproductive health community; and members of ECSAOGS from at least 15 African countries. The theme of the conference was "taking reproductive health to the people"; thus, the issue of obstetricians' and gynecologists' responsibilities to their clients and community was given high priority in the agenda. This forum was the first of its kind in this region of Africa, bringing together international guests to share their experiences regarding different strategies for reducing maternal deaths associated with pregnancy and childbirth complications.

Implementing Organization(s): Population Council

Collaborating Organization(s): East, Central, and South African Obstetrical and Gynaecological Societies (ECSAOGS)
Ethiopian Society of Obstetricians and Gynecologists (ESOG)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance for the Development of a Reproductive Health Strategy in Ethiopia

Part of project Number/s: **03200**

Country/ies: Ethiopia

Technical Coord.: John Skibiak

Period: September 1999 – November 2001

Objective: To provide technical assistance to a working group for the development of a reproductive health strategy for Ethiopia.

Final Report:

The 1997 Ethiopia Reproductive Health Needs Assessment—conducted by UNFPA, WHO, and the Population Council under the auspices of the Ethiopia Ministry of Health (MOH)—used qualitative data to examine Ethiopia's reproductive health environment. The Ethiopia MOH and reproductive health community responded positively to the report. Collaborating institutions were asked to work together to devise a national reproductive health strategy and agenda. The Council's Expanding Contraceptive Choice (ECC) project played a significant role on the committee formed to undertake this work.

As part of the Council's participation in this project, ECC staff provided technical assistance for an evaluation of the national Norplant® program (April 2000–February 2001) and for a subproject testing whether expanding young people's access to coital-dependent contraceptive methods affects contraceptive use (see "Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities in Ethiopia").

During Year Three of the Population Council Program III, a subproject was developed to test the effect of introducing emergency contraception in family planning clinics run by nongovernmental organizations. This subproject sought to expand the existing knowledge base in at least four broad areas critical to the introduction of emergency contraception services. It sought to: (1) enable health care providers and planners to gauge the potential utilization of emergency contraception services among women at risk of becoming pregnant; (2) identify the range of potential barriers limiting timely access to emergency contraception services; (3) determine the most appropriate format(s) for administering emergency contraception pills; and (4) assess the likely impact of emergency contraception services on other reproductive health services. This study was cancelled as a result of the termination of the ECC project.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ethiopia Ministry of Health
Family Guidance Association of Ethiopia
United Nations Population Fund
World Health Organization

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to Evaluation of the National Norplant® Program of Ethiopia

Part of project Number/s: **03200**
Country/ies: Ethiopia
Technical Coord.: John Skibiak
Period: April 2000 – February 2001
Objective: To evaluate Ethiopia's national Norplant program.

Final Report:

Norplant has been available in Ethiopia since 1994. In 1997, the Ministry of Health (MOH) expanded availability of the method. At the same time, however, a number of concerns arose over the quality of implant services. The 1997–98 WHO Reproductive Health Needs Assessment found that, despite the implant's popularity, the rapid expansion of services had given rise to a number of logistic and other operational constraints, including periodic stockouts. Another concern was the ability of existing training programs to transfer the requisite knowledge and skills required. Finally, there was concern about the lack of adequate mechanisms for client follow-up.

In response, an evaluation was conducted of the national Norplant program. As part of its ongoing technical assistance to the MOH (see previous page), ECC was asked to participate in this evaluation. Specific objectives included assessing the place of contraceptive implants in primary health care services and documenting how the introduction of implants satisfied users' needs, fit within service-delivery capabilities, and expanded contraceptive choice. In addition, the results of the evaluation became the foundation for data-based recommendations as to whether contraceptive implant introduction should be expanded and scaled up to the rest of the country.

ECC provided technical assistance for the design of the evaluation during Year One and for its implementation in Year Two of the cooperative agreement. The first phase of implementation gathered information on the origins, availability, and quality of Norplant services in Ethiopia. The second phase synthesized the information from Phase One and indicated that Ethiopia has high unmet need for appropriate contraceptive methods and that Norplant could reduce such unmet need by expanding the method mix.

The evaluation recommended improving the mechanisms for follow-up of clients; overcoming the inconsistencies in the multitude of guidelines, protocols, and training curriculums currently used to support the delivery of Norplant services; maintaining adequate stocks of implants, insertion equipment, and supplies; and enhancing the quality, quantity, and accuracy of information about Norplant implants. It also recommended that any expansion of Norplant services must be incremental.

The results of the evaluation have already yielded results. Both UNFPA and USAID have placed new orders for Norplant kits, and efforts are currently underway by the MOH to implement key recommendations from the evaluation.

Implementing Organization(s): Population Council
Collaborating Organization(s): Consortium of Family Planning NGOs in Ethiopia
Ethiopia Ministry of Health
Family Guidance Association of Ethiopia
United Nations Population Fund/Ethiopia
USAID/Ethiopia
World Health Organization

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities

Part of project Number/s: **03200**
Country/ies: Ethiopia
Technical Coord.: John Skibiak
Period: December 2000 – August 2003
Objective: To increase the use of family planning methods among young people by improving access to technologies that address their unique needs and concerns.

Activity Description:

The 1997 Ethiopia Reproductive Health Needs Assessment found that despite access to modern contraception many young people continue to engage in unprotected sex. Some young women said they felt uncomfortable taking pills or injections on a regular basis when the frequency of their sexual activity was so sporadic. While providers stock some barrier methods, these methods represent only a small percentage of the method mix in Ethiopia.

This study, implemented by the Family Guidance Association of Ethiopia (FGAE) with technical assistance and financial support from the Expanding Contraceptive Choice project, was designed to test the hypothesis that giving young people greater access to contraceptive methods that reflect the distinctive nature of their sexual behavior would increase their use of those methods and of family planning in general, resulting in fewer unplanned pregnancies and greater use of modern family planning methods. To test the hypothesis, FGAE adopted a quasi-experimental research design, drawing the experimental and control groups from its national network of eight youth centers.

At the experimental sites, access was expanded to coital-dependent methods, including methods already available in nongovernmental organization clinics (e.g., male condoms and foaming tablets) and newer technologies (e.g., female condoms and emergency contraception [EC]). The study explores whether the introduction/reintroduction of these methods will strengthen the quality of youth-centered services and expand contraceptive choice by assuring adequate contraceptive stocks, increasing knowledge of family planning, offering dual protection, and removing barriers that impede access to all methods. Results will provide FGAE and other youth-centered service providers with the knowledge, skills, and strategies required to respond more effectively to the needs of young people, to improve the quality of reproductive health services, and to more smoothly introduce new contraceptive methods into the Ethiopian family planning method mix.

Final Report:

This study was designed to test the hypothesis that greater access to contraceptive methods that reflect the distinctive nature of young people's sexual behavior will increase their use of those methods of family planning in general. For reasons related to data collection and methodology, the hypothesis was never conclusively proven; nonetheless a number of important lessons emerged from this study.

One major finding is that the effectiveness of interventions would be better measured longitudinally within individual youth centers, because of significant differences among these centers in Ethiopia. While the study was designed to compare centers cross-sectionally, data analysis was frustrated by the degree and magnitude of variations among centers. While comparisons between control and project sites as a whole

did not produce conclusive results, the impact of specific changes—not all of which were directly related to the project interventions—could be clearly ascertained within individual centers. The study produced a number of interesting findings regarding the feasibility of providing coital-dependent methods to adolescents through youth clinics in Ethiopia. The most notable of these are outlined below.

Repackaging various methods into a single youth-friendly "brand" significantly increased demand. The desirability of repackaged products was most clearly demonstrated in the case of male condoms (MCs), where the product's popularity quickly led to unanticipated stock-outs and distribution bottlenecks.

Product availability was directly correlated with utilization. Utilization of the methods increased when repackaged supplies were available, and dropped when they were exhausted. This finding reinforces the need to ensure the continuity of contraceptive supplies, especially those targeted specifically toward youth.

Provider attitudes toward distribution also influenced utilization. While availability was a central factor in determining usage, provider attitudes and approaches to distributing supplies also exercised a significant influence over acceptance rates. Some staff at youth centers "hoarded" the popular repackaged MCs in order to conserve supplies, which ultimately reduced the total number of users. Conversely, demand for foaming tablets remained low despite adequate stocks, largely because providers were not enthusiastic about their potential appeal to adolescents. These findings suggest the need to develop uniform service delivery strategies that reflect the special concerns of adolescents, especially in regard to ECPs.

Costs of repackaging supplies, especially ECPs, are unsustainable. Despite the increased demand for and utilization of repackaged methods, especially condoms and ECPs, it was ultimately found that the monetary and logistical costs associated with repackaging were prohibitive for scaling-up. This finding highlights the utility of introducing a dedicated ECP product into Ethiopia.

In addition to these findings, which were directly related to the interventions introduced under this project, several external factors, such as fluctuations in numbers of PSPs and the launch of new activities not related to this project, also exerted notable impact on project outcomes, making comparisons between control and intervention sites less meaningful than longitudinal examinations of individual clinics.

In recognition of the contributions of this project, the Ethiopian Federal Ministry of Health requested assistance from the Population Council to develop a new project to scale-up the results of this study. With funding from the Hewlett and Concept Foundations, this new project focuses on mainstreaming ECPs in the public sector. With the participation of FGAE and other local partners, a dedicated in-service EC training curriculum was drafted and reviewed by key stakeholders. Ethiopia's drug regulatory board is processing the registration of a dedicated ECP and has approved the importation of 40,000 units of product for use by the study. Finally, efforts are underway to incorporate EC into the pre-service training curriculum of Ethiopia's three principal medical schools.

Implementing Organization(s): Family Guidance Association of Ethiopia (I00.106A)

Collaborating Organization(s): DKT Ethiopia
Doctors Without Borders International

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 1.2

Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two

Project Number/s: **03253**
Country/ies: Zambia
Technical Coord.: Saumya RamaRao
Period: September 2000 – January 2004
Objective: To provide information on contraceptive use patterns and dynamics after the introduction of Norplant.

Activity Description:

The Lusaka Impact Study is being implemented through the Population Council's Quality of Care Impact project and received funding and technical assistance from the Expanding Contraceptive Choice project. The purpose of the study is to assess whether continuation of contraceptive use will be increased and unintended pregnancies reduced with greater choice of methods. To test this hypothesis, the study made use of the pilot introduction of Norplant and the reintroduction of Depo-Provera within Zambia's family planning program. Two groups of clinics in which these contraceptives were added to the existing method mix were compared to a control group of clinics with an unchanged method mix. In one group of experimental clinics, both Norplant and Depo-Provera were added to the method mix; in the second only Depo-Provera was added. Eight public-sector clinics in Lusaka city participated in the study; two in each of the experimental groups and four in the control group.

Under Phase One of this project (May 1998-September 1999; funded under the previous Population Council Program cooperative agreement CCP-A-00-94-00013) a client-flow analysis and a situation analysis were conducted in all eight clinics, a panel of 3,203 family planning users was recruited and interviewed, and 2,200 women from the panel were interviewed during a three-month follow-up. Two reports were prepared based on the client-flow analysis and results from the baseline panel and three-month follow-up interviews. In addition, an in-country dissemination meeting for Ministry of Health and USAID Mission stakeholders was held in July 2000.

Phase Two of the study consisted of a final round of data collection. Between January and May 2001 both a situation analysis and a follow-up interview with panel respondents were conducted. The situation analysis measured changes in service quality in the eight clinics since the baseline measure. The follow-up interview was done at a cohort age of approximately 24 months. (Note: The original proposal was for follow-up interviews at cohort ages 3, 15-17, and 27-29 months; however, given the high rate of loss to follow-up at the three-month interview [32 percent] and lack of resources, the design was modified for only one follow-up interview at 24 months.)

Final Report:

The Population Council Program III provided support for the second phase of the Lusaka Impact Study. The intervention involved the addition of new contraceptive methods, Norplant and Depo-Provera (DMPA), effective provider training, and adequate contraceptive supplies and equipment. The study examined the effect of the intervention on quality of care, provider's knowledge and attitude, and client behavior.

The study consisted of 8 public sector clinics in Lusaka, Zambia which were classified into 3 levels. In addition to program methods (combined and progestin-only pills, male and female condoms, foam,

Noristerat, IUD, NFP, LAM, and emergency contraceptives), level A offered DMPA and Norplant®; level B offered DMPA, and level C offered no additional methods. The baseline data collection began in 1998 and the follow-up occurred between January and May of 2001. A total number of 3,203 clients from all the clinics were recruited at the baseline and 1,469 were re-interviewed at the follow-up.

Results indicate that the intervention had some effect on expanding contraceptive choice. Family planning guidelines were used by all providers at clinic levels A and B, suggesting that they are especially useful to answer questions, solve problems and clarify counseling issues where new methods have been introduced into the method mix. Some providers in level C reported providing referrals for Norplant or offering it themselves, which can be due to staff turnovers and transfers leading to diffusion. However, this did not translate into higher levels of knowledge about the additional methods. Training of providers in levels A and B did not result in higher levels of knowledge about added methods when compared to providers in level C sites, suggesting that the addition of more methods may overwhelm rather than strengthen the service delivery system. The results from the provider interviews also suggest that the majority of providers, regardless of clinic level, counsel clients to use condoms to prevent RTI/STIs and provide HIV/AIDS information to family planning users.

Only one third of clients interviewed at baseline were followed limiting the conclusions that can be drawn about the impact of the intervention on clients' contraceptive knowledge and behavior. Respondents at levels A and B sites, from either the follow-up cohort or exit interviews, did not have significantly greater knowledge about contraceptive methods, particularly those that were added to the method mix (Norplant and Depo-Provera), than clients at level C sites. The introduction of methods at clinic levels A and B seemed to be associated with an increasing percentage of women not wanting their last pregnancy and a decrease in the percentage of women wanting their pregnancy later. Although there appeared to be an effect on clients' attitudes towards reproductive intentions and desire to space, there was no evidence of change in clients' behaviors towards contraceptive use. A complete method mix was frequently unavailable, which presumably influenced clients' continuation rates as well as their ability to freely choose or switch between methods. There were instances of stockouts; further, field reports indicated that the supply of Norplant to level A facilities was not always continuous. The highest level of contraceptive use is among respondents who visited facilities with the narrowest range of contraceptive methods, contrary to our expectations. Further, it appears that Depo-Provera has substituted Noristerat as an injectable contraceptive, though the level of injectable use is similar across all levels. We were not able to see any demonstrable increase in contraceptive continuation among respondents in level A, which could be related to the fact that only 5% of users chose Norplant at the baseline.

This mix of findings should guide implementers to identify these areas of weakness and further strengthen basic and refresher training, ensure adequate supplies and equipment, and improve other mechanisms that had been put in place in the levels A and B clinics.

A copy of the final report detailing the points listed above and the overall outcomes of the Lusaka Impact Study was submitted to USAID in June 2004.

Implementing Organization(s): Central Bureau of Statistics, Lusaka, Zambia (I00.83A)
Population Council

Activity Funding: Field Support & Pop Core

Contribution to Results Framework: IR 1.2

Expanding Contraceptive Choice Demonstration Project in the Copperbelt Province of Zambia: Transition Phase

Project Number/s: **03254**
Country/ies: Zambia
Technical Coord.: John Skibiak
Period: January 2001 – June 2001
Objective: To develop and implement a package of integrated service delivery in the Copperbelt Province of Zambia with the goal of enhancing contraceptive choice and quality of care nationwide.

Final Report:

Between late 1996 and early 1999, ECC and the World Health Organization Special Programme of Research, Development, and Research Training in Human Reproduction (WHO/HRP) supported a pilot study in Zambia to develop and test a package of integrated family planning services for expanding contraceptive choice. Implemented by the Zambia Central Board of Health (CBoH) and CARE, the study (1) trained health care providers in the rural Copperbelt to deliver high-quality family planning and reproductive health services; (2) introduced three new contraceptive methods (Depo-Provera®, emergency contraception, and female condoms) and established referral systems for methods not available locally; (3) provided routine technical backup to field-based staff; and (4) supported ongoing logistics systems to avoid contraceptive stockouts. In May 1999, the study was extended to enable CARE and CBoH to synthesize the results to date and to apply that information in such a way that all the tools, strategies, and action plans needed to replicate the strategy would be well in place.

USAID and WHO reacted favorably to the preliminary pilot findings, and both institutions support scaling up the activity. The purpose of scaling-up activities will be to assess whether the methods used in the pilot study can be replicated in a wider setting, with the goal of improving the quality of service delivery and expanding contraceptive choice nationwide. However, prior to scaling up the activity, several tasks remained to be completed. These tasks were accomplished during a transition phase.

During this transition phase, a dissemination workshop was held 25 January 2001 in Ndola for stakeholders and other interested parties. ECC staff (including project director Suellen Miller), regional project coordinator Mary Zama, other project team members, and stakeholders met to disseminate the results and discuss the next steps for scaling up the project. Also during this transition phase, a draft proposal for scaling up was developed. The final proposal is expected to be completed by February 2002. USAID/Zambia has provided field support to fund the scaling-up effort.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt

Project Number/s: **03262**
Country/ies: Zambia
Technical Coord.: John Skibiak
Period: June 2001 – August 2005
Objective: To expand contraceptive choice and increase the availability of high-quality reproductive health services across eight rural and peri-urban districts of the Copperbelt; to field test a model for scaling up reproductive health interventions; and to support ongoing discussions over the approval and registration of Depo-Provera® and emergency contraception and serve as a model for the introduction of these methods at the national level.

Activity Description:

In 2001, the Population Council and the Zambia Central Board of Health, in consultation with WHO and USAID/Zambia, launched a "transition phase" to explore the managerial, technical, and other adaptations required to scale up a pilot study on expanding contraceptive choice (see "Expanding Contraceptive Choice Demonstration Project in the Copperbelt Province of Zambia: Transition Phase"). In May 2002 the Copperbelt Provincial Health Office launched a two-year effort to scale up a package of service delivery interventions introduced in the pilot study. The intervention, called Pilots to Regional Programs (PRP), has two broad goals: (1) to bring the benefits of the pilot study to thousands of men and women across Zambia's Copperbelt Province; and (2) to test if the model overcomes barriers that typically undermine efforts to scale up pilot interventions, namely, the ability to maintain quality while increasing the quantity of intervention efforts, the need to respond meaningfully to larger, more heterogeneous social contexts, and the capacity to maximize economies of scale.

The project introduces a package of three intervention components, including: (1) expanding the range of contraceptive methods available to family planning clients; (2) training health care workers more effectively and efficiently; and (3) bringing together communities and the health care system so that reproductive health needs can be met more easily and effectively. The primary goal of the first phase of the scaling-up effort is to establish a limited number of demonstration sites or "centers of excellence" in each of the eight participating health districts, thereby providing them with firsthand exposure to the broad range of potential support activities possible through the project. The second phase entails a process of reflection and analysis, culminating in the formulation of district-specific implementation plans. During the third phase, a period of 15 months, the project assembles the human and financial resources needed to implement and sustain the scaling-up effort in the eight districts by employing a management structure that is fully integrated with existing public sector structures.

Final Report:

Following the year-long transition phase, the PRP Initiative was launched in May 2002, and has since earned itself the reputation as being one of the most innovative and cost-effective programs in Zambia for delivering high-quality family planning services in rural and peri-urban areas. With its three-phase implementation plan and thematic focus on expanding contraceptive choice, innovative training, and broad community outreach, PRP has proven itself to be a viable and sustainable model for bringing to scale health interventions previously introduced on a pilot basis.

Expanding contraceptive choice: Contraceptive prevalence in the eight participating districts is now among the highest in rural Zambia, with women in these districts having access to methods and services typically available only in urban settings. In the last three years, the number of new contraceptive users at the 37 participating health centers has risen steadily — from 3,000 to almost 14,000 per quarter. Importantly, the increase has not skewed the method mix or biased the provision of some methods over others.

Innovative training: PRP also achieved notable success in the development and implementation of sustainable training programs, including a traditional classroom approach for training of trainers (TOTs), and an on-site self-directed learning program for rural providers at small health care facilities. But even more importantly, the three-phased intervention process allowed districts to adapt the programs' content and timing to local variations in staff attrition, service expansion, and resource availability. As a result of this flexibility, the districts succeeded in training over 120 formal sector service providers — seven times the number trained during the entire life of the initial ECC pilot study. The districts also brought on board 205 community-based distributors and well over 500 community-based Standard Days Method counselors.

Community outreach: Expanding community outreach also saw notable achievements in terms of disseminating information, involving local leadership, and maximizing economies of scale. PRP introduced newsletters and other dissemination strategies that brought to life many of the Initiative's major accomplishments and findings. It also actively involved community members and leaders as advocates for behavior change. Finally, PRP maximized economies of scale by encouraging districts to pool assets and exchange material resources such as transport, training facilities, equipment and supplies. By the end of Phase Three, districts were holding joint trainings; collectively procuring equipment, supplies and commodities; and collaborating on activities they once pursued on their own.

Though borne out of the need to replicate a series of successful pilot interventions, the PRP Initiative has proven to be a flexible, innovative, and sustainable framework for guiding the scaling-up of pilot interventions. Today, all eight of the Copperbelt's rural and peri urban districts have an organizational framework established for supporting PRP interventions that is fully integrated into their existing administrative structures and fully paid for by the districts themselves. The Zambia Ministry of Health has identified PRP as one of its best practices in reproductive health and has selected the PRP framework as its model for scaling-up reproductive health services over the next decade. An article on the PRP experience is currently under review for publication in a volume of case studies on the scaling-up of pilot interventions to be published next year by WHO / Reproductive Health and Research, and a proposal is being prepared for securing external donor funding to scale up PRP nationally.

Implementing Organization(s): Copperbelt Provincial Health Office, Zambia Central Board of Health (I02.16A)
Population Council

Collaborating Organization(s): Georgetown University Institute for Reproductive Health
Planned Parenthood Association of Zambia
Reproductive Health Alliance Europe
World Health Organization

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Technical Assistance to the Zambia Ministry of Health for the Development of a National Reproductive Health Strategy

Part of project Number/s: **03200**

Country/ies: Zambia

Technical Coord.: John Skibiak

Period: August 2001 – June 2002

Objective: To provide technical assistance to the Zambia Ministry of Health for the development of a national reproductive health strategy, which includes the registration of Depo-Provera® and the selection of a dedicated emergency contraception pill (ECP).

Final Report:

Over the last six years, recognition of the importance of contraceptive choice has increased markedly in Zambia. Previously, the issue of choice took a back seat to the convictions of health care planners. During the 1995 Zambia Contraceptive Needs Assessment, for example, there was little debate or concern when provider biases precluded consideration of several contraceptive methods, notably injectable contraceptives, for inclusion in the national method mix. Many in Zambia's reproductive health community credit the Population Council for playing a key role in raising awareness of the importance of contraceptive choice in this country.

In Au gust 2001, the Zambia Ministry of Health's Central Board of Health established a subcommittee within the National Reproductive Health Task Force to formulate recommendations on the procurement, reintroduction, and registration of injectable contraceptives and ECPs. Staff from the Council's Expanding Contraceptive Choice (ECC) project supported this subcommittee's work by researching, procuring, and submitting to the subcommittee extensive documentation on the contraceptive methods under consideration. The Council opened channels of communication between the subcommittee and the manufacturers of various methods (Gideon Richter, NorLevo, Pharmacia, and Schering). Council researchers summarized and documented the results of their research in Zambia and provided analyses of the cost, quality, and sustainability of various reproductive health services.

In November 2001, the subcommittee decided to pursue the introduction of Depo-Provera® and emergency contraception in Zambia. The subcommittee established a short-term consultancy (funded by the UK Department for International Development) to justify introducing these methods and to define a plan of action for doing so. The Council was invited to review the terms of reference in the contraceptive-introduction documentation and to support the effort in any way possible. ECC staff advised the subcommittee on overseeing the consultancy and assisted the consultant (Peter Hall, Reproductive Health Alliance Europe) in gathering information relevant to his work. We provided him with research results from earlier emergency contraception and Depo-Provera® studies; retrieved data from CARE and PPAZ (both have provided Depo-Provera®); and created links between the consultant, the USAID Mission, and its cooperating agencies in Zambia. We also developed a research project (submitted separately to the Compton Foundation) that addresses the question "Do dedicated emergency contraception pills make a difference by increasing contraceptive prevalence and lowering unwanted pregnancies?" Results of this research would help the subcommittee to answer questions concerning procurement of a dedicated ECP.

Collaborating Organization(s): Zambia Central Board of Health

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Searching for Synergies: Dual Protection Within the Context of Provider-Dependent Contraception

Project Number/s: **03265**
Country/ies: Zambia
Technical Coord.: John Skibiak
Period: February 2003 – August 2005
Objective: To draw on the experience of the "Pilot Interventions to Regional Programs" (PRP) Initiative as a means for better understanding the factors that influence the use of dual protection (DP) by family planning clients and the effectiveness of programs that seek to promote it.

Activity Description:

Dual protection (DP) refers to the use of one or more methods in order to provide protection against both pregnancy and STIs. As one of its cornerstones, Zambia's PRP Initiative stressed the use of DP. From the outset of the three-year project, lessons on DP were included in the training of all health care providers. New management information systems were developed and implemented to measure dual method use. The project introduced female condoms into the rural Copperbelt Province for the first time and increased access to them by procuring stocks for free distribution. Supervisors were vigilant in encouraging field staff to support DP. Despite these efforts, however, promotion of DP under PRP registered relatively few gains. DP clearly paled in comparison to the dramatic increases in overall contraceptive prevalence and lagged behind the acceptance of relatively novel contraceptive options such as the Standard Days Method.

To help understand the relatively slow uptake of DP, this study will undertake a rapid, yet in-depth review of the PRP experience. It will use this experience as a case study to explore all aspects of DP — from the perspectives of the service delivery system, of providers at the field level, and of potential DP users.

This exercise will look at both the supply side (programmatic requirements) and the demand side (user perspectives and needs) of DP. Key activities will include: reviewing PRP service delivery statistics to compare trends in single and dual method use, disaggregated by method combinations and age cohort of the family planning client; surveying health care providers to identify the programmatic and other operational factors that may have facilitated or impeded the promotion of DP strategies; conducting discussions with health care providers and district supervisors to review the effectiveness or inadequacy of PRP strategies aimed at facilitating DP promotion; and conducting in-depth interviews with potential DP users, with a view towards better understanding the decision-making processes influencing their choice.

Final Report:

Drawing on the experiences of the PRP Initiative, based in the Copperbelt Province of Zambia, this study examined the factors influencing uptake of DP. It incorporated quantitative and qualitative research methods, and sought input from both providers and potential DP users. By the end of the study, the following data collection activities had been undertaken: quantitative review of service statistics (2002 to 2005) at 37 PRP-supported facilities; structured interviews with 87 family planning providers at the same 37 facilities; focused interviews with 26 users and 50 non-users of DP, drawn from four districts selected for their relatively strong or poor performance at delivering DP; and participatory data review workshops with providers and supervisors from the four districts.

The research showed that some barriers to the uptake of DP rested at the level of health care providers. In fact, the concept of 'dual protection' was widely misunderstood among providers, most of whom (96%)

defined it solely as a combination of two methods (rather than as protection again both pregnancy and STIs). Furthermore, instead of being considered a contraceptive option for all couples, DP was seen by providers to be most useful in preventing HIV transmission in high-risk clients, with 81% of providers stating that they would recommend it primarily to non-monogamous couples and/or individuals with multiple sex partners, and 78% saying they would encourage its use by HIV discordant couples.

Additionally, the data provided important insights into key attributes of DP users. All were married, 77% were over 30 years of age, and at least 69% had completed one year of high school. The data showed that, when practiced, DP typically entailed the addition of condoms to an existing method. The data also highlighted resource and personnel factors inhibiting the use and provision of DP: training, supervision, and support for DP providers were perceived to be insufficient; frequent stock-outs of preferred methods disrupted use of all methods and discouraged clients from resuming when stocks became available again; and accurate clinic-based record keeping was hampered by the availability of condoms from outside sources and shortcomings in record keeping formats and practices.

Finally, community perceptions of DP and the cultural context of contraceptive use also impeded the uptake of DP in the study area. Given the confusion of DP with dual method use, many community members do not see the logic in using two methods. Additionally, while women tend to initiate DP use, most frequently in response to concerns over the fidelity of their partner (reflecting a high personal risk perception for contracting HIV), their negotiating power is low.

Based on these findings, the following set of recommendations has been assembled in order to assist programs in promoting DP among family planning clients:

1. Intensive provider training, supervision, and oversight is imperative;
2. Contraceptive stock-outs must be managed to maintain continuity of single and dual method use;
3. During the early stages of DP introduction, focus should be placed on married couples who have completed childbearing as they are most likely to be initially receptive; and
4. Women need to be better equipped to successfully negotiate condom use, and men need to be sensitized to the benefits of condom use in general, and of DP in particular.

Implementing Organization(s): Population Council

Collaborating Organization(s): Copperbelt Provincial Health Office, Zambia Central Board of Health

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Reducing Unwanted Pregnancy Among Victims of Sexual Assault: New Windows of Opportunity for Emergency Contraception

Project Number/s: **44103**
Country/ies: Zambia
Technical Coord.: John Skibiak
Period: July 2004 – August 2005
Objective: To better understand the support-seeking behaviors of sexual assault survivors; to demonstrate the feasibility of a simple intervention that familiarizes first point of contact (FPC) staff with the full range of support services available to assault victims and guarantees timely access to quality emergency contraception (EC) services at victims' FPCs.

Activity Description:

This study, carried out in three districts of Zambia's Copperbelt Province, is designed to test the feasibility of an intervention ensuring that no window of opportunity closes before a sexual abuse victim receives the services she needs — particularly services that could prevent an unwanted pregnancy.

The intervention comprises three components. The activity will begin with a rapid assessment designed to provide insight into the extent and nature of sexual violence in the target area and into victims' support-seeking behaviors. While popular perception holds that sexual assault has dramatically increased in recent years, little reliable crime statistics exist. This assessment will help shed light on these claims and identify the institutional FPCs from which survivors seek services in the hours following an assault. The data, which will highlight trends in support-seeking behavior and community perceptions of health and legal services offered by FPCs, will be used to inform and guide all subsequent phases of the study. Building on identified needs, the second activity will orient all FPC staff to the full range of health, forensic, legal, and psycho-social services available to sexual assault victims in order to enhance their access to support services, including those not directly provided at FPCs. Finally, the intervention will train staff at selected FPCs to provide EC services to rape victims who might not otherwise receive them within 72 hours of unprotected sex. It will strengthen FPCs' capacities to offer EC services by supporting efforts at information dissemination and community outreach. Initially, the selected FPCs will include the Victim Support Unit of the Zambia Police Force, district health clinics, and hospitals located in the three districts.

Additionally, in keeping with the philosophy of the WHO Strategic Approach to Contraceptive Introduction, this intervention will seek to use the expansion of EC services as a vehicle to strengthen the entire support system for victims. It will use the strengthened support system as a basis for re-introducing, after a lapse of nearly five years, a dedicated EC pill into Zambia's public sector service delivery system. Finally, the study will support a host of initiatives already underway in Zambia, including, among others, ones chaired or sponsored by the Zambia Central Board of Health, Development Services and Initiatives/Southern Africa (DSI), and organizations such as CARE International, Women for Justice, and the Juvenile Court, to combat gender-based violence and address its consequences.

Final Report:

In thirteen months of operation, this project achieved its primary objectives:

The rapid assessment of sexual assault and support-seeking behaviors in the Copperbelt Province produced the empirical foundation for the remainder of the activity and provided insights into the demographic

characteristics of survivors, the FPCs from which they seek support, and the likelihood of arrival at an FPC in time to prevent pregnancy. A comprehensive record review of all rape, defilement, and incest cases reported to police and health care facilities throughout the Province between 2001 and 2004 found that most sexual assault victims are young, with the largest cohort consisting of girls aged 10-14; another one-third of cases affect women aged 15-49. The first point of institutional contact is usually the police, followed by health care providers, and most survivors who seek help from both the police and health care providers do so within 72 hours of the assault — within EC's window of effectiveness. Timely arrival at the hospital is no guarantee of EC access, however; only 37% of eligible women received EC during treatment.

Not all sexual assault survivors seek institutional support, and anecdotal evidence suggests that very few do. Community focus groups were conducted to better understand the perceptions and motivations of women seeking support, and data was gathered from four sites in July 2005. Barriers to reporting sexual assault, including social stigma (especially when the perpetrator is a family member) and financial costs (both official and unofficial) incurred at police and health facilities are high. Women from vulnerable groups are most likely to report to the police; conversely, justice is seen as most accessible to the relatively wealthy who can shoulder litigation costs.

In keeping with the WHO Strategic Approach, these findings were then used to guide the introduction of EC services in specific sites and to strengthen institutional capacity more generally. In early August 2005, a workshop was convened in Ndola that, for the first time, brought together over 50 representatives from the police, health, and legal sectors in order to collectively discuss institutional responses to sexual assault and the full range of services available to sexual assault victims. Each day of the three-day meeting was devoted to a different sector and included informational sessions, question-and-answer periods, and field visits to Ndola's Central Police Station, Central Hospital, and District Court.

In the final phase of the study, EC was provided to sexual assault survivors through health care and police facilities. Service provision through health care facilities began immediately after a training of 32 doctors and nurses was conducted in August 2005 which followed the curriculum and service delivery protocol developed for this project. Responding to the need identified by community focus groups, these providers and police participants also attended a day-long training on psycho-social counseling skills. While the Zambian Police Force enthusiastically supports EC provision by their officers, concerns from the health sector have delayed their participation in this intervention. An agreement was reached between the two camps at the August workshop, providing a tangible example of the collegiality fostered by the meeting, and a letter of understanding is currently being prepared by the Ministries of Health and Home Affairs. Due to this delay, this third intervention remains in its initial phases. However, the intervention will continue with funding from ECafrique, Hewlett, and possibly SIDA. A final report is expected in mid 2006.

Implementing Organization(s): Population Council

Collaborating Organization(s): ECafrique
Ndola Central Hospital
Zambia Central Board of Health
Zambia Police Forces, Victim Support Unit

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

West and Central Africa Region

Regional Summary

Expanding Contraceptive Choice (ECC) program objectives in the West and Central Africa (WCA) region were implemented by staff in Dakar, Senegal with direction, assistance, and support from New York–based program staff. The program worked in partnership with regional governmental and nongovernmental organization (NGO) partners to promote the use of evidence-based recommendations for improving the quality of family planning services, and to promote further appropriate research, with a focus on research leading to expanded contraceptive options, particularly for underutilized technologies with perhaps the best potential to address users' unmet needs for family planning and for dual protection from both pregnancy and sexually transmitted infections (STIs).

In Senegal, research was conducted in collaboration with the Ministry of Health, Hygiene, and Prevention's (MOH) Division of Reproductive Health to evaluate the quality of Norplant® contraceptive implant services offered under the national family planning program, and to determine the feasibility of and strategies for scaling up the method, and the potential role of newer generation implant technologies such as Jadelle®. A retrospective cross-sectional study was conducted over two phases.

The study found that Norplant, despite its associated side effects and provider-dependent nature, was highly appreciated by some users, and suggests that the method has great potential to continue to address the large unmet need for birth spacing and birth limiting in Senegal, including for clients with no previous contraceptive experience. The study also suggested the need to address gaps in monitoring, tracking, and following up time-dependent methods such as implants. Research findings were instrumental in generating discussions among stakeholders about the needs of clients, providers, and the community for better quality family planning information and counseling. Recommendations offered by stakeholders at the July 2002 dissemination meeting hosted by the Population Council and the MOH included the need for improved client follow-up mechanisms and broad support for making Norplant more widely available and accessible.

ECC was also effective on the executive board of the Francophone Maximizing Access and Quality (MAQ) Subcommittee as a research and technical support partner. The subcommittee was established in 2000 to develop MAQ activities in west and central Africa with a focus on integrating STI services into reproductive health protocols in the region. ECC worked in collaboration with subcommittee colleagues to assess the extent in four countries of STI prevention information in reproductive health protocols and to conduct formative research. While most of the countries had incorporated some information about STIs into their protocols, many protocols were incomplete and did not specify how to offer STI services in the context of providing general reproductive health, family planning, and postabortion services. The partnering CAs then surveyed reproductive health providers in the four countries to assess their familiarity with the STI components of protocols; how they incorporated these components into their practice; and how they felt the protocols could be improved through more comprehensive integration of STI services. Findings were disseminated in-country and regionally in 2002.

Launching the Regional Francophone MAQ Subcommittee

Part of project Number/s: 03200

Country/ies: West and Central Africa Region

Technical Coord.: Penda N'Diaye, Rasha Dabash

Period: July 2000 – October 2001

Objective: To launch a Francophone MAQ Subcommittee to support the global MAQ initiative.

Final Report:

USAID's Maximizing Access and Quality (MAQ) Initiative brings together USAID staff, cooperating agency (CA) community members, and program managers to identify and implement practical, cost-effective, focused, and achievable interventions aiming to improve access to and quality of family planning and selected reproductive health services. In 1995, decisionmakers and health professionals from ten Francophone countries in West and Central Africa gathered for a regional conference in Burkina Faso to discuss and disseminate lessons learned through the MAQ initiative and to develop national MAQ action plans. An ad hoc committee was established to create a permanent regional Francophone MAQ Subcommittee to the MAQ Steering Committee. The subcommittee consisted of USAID staff, senior technical professionals from Francophone Africa, and representatives of CAs active in the region.

At the request of USAID, the Population Council, in collaboration with JHPIEGO and INTRAH/PRIME II, organized a meeting in Dakar, Senegal in July 2000 to establish the Francophone MAQ Subcommittee. The Council's Expanding Contraceptive Choice medical associate for the region, Penda N'Diaye, was elected to serve on the subcommittee's executive board. In February 2001, the executive board convened to refine the objectives of the subcommittee. N'Diaye was instrumental in placing dual protection (against unwanted pregnancy and sexually transmitted infections) on the subcommittee's technical agenda.

In July 2001, INTRAH distributed the final report of the February 2001 subcommittee executive board meeting.

Implementing Organization(s): Population Council

Collaborating Organization(s): INTRAH/PRIME II
JHPIEGO

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to the Francophone MAQ Subcommittee to Develop Activities in West and Central Africa

Part of project Number/s: **03200**
Country/ies: West and Central Africa Region
Technical Coord.: Rasha Dabash
Period: July 2000 – June 2002
Objective: To develop MAQ activities in West and Central Africa in adherence with guidelines established by the global MAQ initiative and with the mandate of the Francophone MAQ Subcommittee.

Final Report:

Since 1995, the Population Council's Expanding Contraceptive Choice (ECC) project has been involved in various activities related to USAID's Maximizing Access and Quality (MAQ) Initiative. In July 2000, a Francophone MAQ Subcommittee was established to develop MAQ activities in West and Central Africa, with a focus on integrating sexually transmitted infection (STI) services into reproductive health protocols in the region (see "Launching the Regional Francophone MAQ Subcommittee"). Since October 2000, ECC project associate Rasha Dabash has attended subcommittee meetings in Washington, DC (in place of Penda N'Diaye, the ECC medical associate for the region, based in Dakar). Dabash worked closely with collaborating agencies and Population Council field staff to assess the extent to which information pertaining to the prevention of STIs, including HIV infection, was included in reproductive health protocols in West and Central Africa.

Following finalization of the Francophone MAQ Subcommittee's mandate, specific objectives, and regional plan of action, ECC staff and colleagues at the nongovernmental organizations INTRAH, Family Health International (FHI), and JHPEIGO conducted formative assessments of national reproductive health norms and protocols in four West and Central African countries. ECC staff conducted a desk review of Senegal's reproductive health protocols and norms; INTRAH, FHI, and JHPEIGO staff conducted similar reviews for three other countries in the region. These reviews revealed that while most of the countries had incorporated some information about STIs into their health-service protocols, many gaps remained. The protocols were incomplete and did not specify how to offer STI services in the context of providing general reproductive health, family planning, and postabortion services.

Following these reviews, the four cooperating agencies (CAs) joined forces to conduct a survey of reproductive health providers in the four countries to assess whether they were familiar with the STI components of protocols; how they are currently incorporating these components into their practice; and how they feel the protocols could be improved through more comprehensive integration of STI services. The standard survey instrument was developed with input from all four CAs. Survey data were analyzed by JHPEIGO; country-specific and regional findings were disseminated in July and August 2002.

Implementing Organization(s): Population Council
Collaborating Organization(s): Family Health International
Francophone MAQ Subcommittee
INTRAH/PRIME II
JHPIEGO

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 1.2

Institutional Support for Regional Professional Societies: Plenary Session on Female Condoms: Introduction and Access at the 8th International Society of Women and AIDS in Africa Conference

Project Number/s: **03256**
Country/ies: West and Central Africa Region
Technical Coord.: Penda N'Diaye
Period: March 2001 – April 2001
Objective: To provide institutional support for the SWAA conference as part of capacity-building efforts.

Activity Description:

The Population Council's Expanding Contraceptive Choice (ECC) program worked to promote cooperation among international, regional, and local family planning and reproductive health communities, addressing the need to share information and lessons learned about expanding access to underutilized contraceptive technologies, such as the female condom. The ECC program had a longstanding involvement with regional professional societies—providing them with technical assistance, conducting trainings and workshops, and collaborating on research studies and interventions. Included among these organizations were the Society of Women Against AIDS in Africa (SWAA); the Latin American Association of Researchers in Human Reproduction; and the East, Central, and South African Association of Obstetrical and Gynaecological Societies. The ECC program provided support for a series of seminars and international meetings held by these organizations during Years Two and Three of the Population Council Program III. This activity provided sponsorship of a plenary session on female condoms at the SWAA 2001 conference, as well as sponsorship of seven SWAA participants' attendance at the conference's strategic planning meeting.

Final Report:

ECC program staff provided support for a seminar on the female condom at the 8th International Society of Women Against AIDS in Africa Conference in Kampala, Uganda, held in April 2001, in order to share their community service delivery models with a broad audience of reproductive health professionals. The theme for this conference was "Children and HIV/AIDS: Challenges and Strategies to Cope." Penda N'Diaye and Mitchell Warren of the Female Health Company co-hosted a plenary session titled "Female condoms: Introduction and access." Dr. N'Diaye presented research and lessons learned from programs conducted in collaboration with SWAA and other STI/HIV-prevention groups that work to improve access to the male and female condoms as dual-protection methods. Dr. N'Diaye also participated in the strategic planning following the conference, where SWAA International's five-year strategic plan was drafted. ECC provided funding for seminar costs and logistics, and sponsorship of seven SWAA participants' attendance at the conference and strategic planning meeting.

Implementing Organization(s): Population Council

Collaborating Organization(s): Society of Women Against AIDS in Africa (SWAA)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Evaluation of the National Norplant® Program in Senegal

Project Number/s: **03251**
Country/ies: Senegal
Technical Coord.: Suellen Miller, Rasha Dabash
Period: July 2000 – August 2002
Objective: To evaluate Senegal's national Norplant program.

Activity Description:

Norplant was introduced into Senegal's national family planning program in 1986. The Expanding Contraceptive Choice (ECC) project, in collaboration with the Senegal Ministry of Health (MOH), conducted a study of the national contraceptive implant program. The study combined qualitative and quantitative research methods to assess implant service delivery and determine the feasibility and strategies for scaling up Norplant or making a transition to Jadelle®. Study objectives were to evaluate the Norplant program by assessing quality of care, method acceptability, percentage of contraceptive users choosing and continuing to use implants; and to gain a profile of implant users—both those still using their first set of implants and those on their second set (reinserters). A crucial aspect of the study was locating women who had Norplant in situ for over five years and were *perdues de vue* (lost to follow-up; literal translation, "lost to sight") in order to determine the reasons why they were lost to follow-up, to advise them of their risk of pregnancy, and to offer them new implants and/or other methods to match their current reproductive intentions.

The study was implemented in two phases. (Phase I was funded under CCP-A-00-99-00013; Phase II under the current agreement.) Phase I provided information on the demographic profile of implant users; the prevalence of Norplant use; and the number of implant users who are active, inactive, and *perdues de vue*. Phase II consisted of individual interviews with women who had Norplant in situ for more than five years as well as those who had multiple insertions.

Results from this evaluation will have an impact on the future of Senegal's implant program and will help the MOH decide whether and how to expand Norplant services or to undertake a transition to Jadelle.

Final Report:

This study was two-phase and diagnostic, using a retrospective cross-sectional study design. Phase I methodologies included the secondary analysis of Norplant literature and assessed the profile of all Norplant users from 1986 to 2000. Phase II methodologies comprised structured interviews with providers, current Norplant clients, reinserters, and clients considered lost to follow-up.

Phase I. Overall, 18,557 Norplant acceptors were found registered between 1986 and the end of the data collection period. The majority of Norplant selectors (12,463) were active users (i.e., they currently had implants at the time of the study). Of these, 10,564 (84.8 percent) were using their first set of implants, which had been in place for less than five years; 5.6 percent had used two consecutive sets of Norplant; 0.1 percent were on their third set; and 9.5 percent were lost to follow-up or had not had a return visit for their scheduled removal. The average age of reinserters was 35.9 years, and they had an average of 4.7 children, indicating they were older and had achieved desired family size. Results of Phase I provided a sociodemographic baseline of the diverse population of women who had selected Norplant over the past 15 years and gave direction for Phase II.

Phase II. The majority of clients lost to follow-up were actually lost to record-keeping (65 percent) and are evidence of the poor management information systems in Senegal for monitoring, tracking, and following up use of a time-dependent method.

Clients and providers recognized the need for additional Norplant information for both clients and the community at large. Information, education, and communication (IEC) materials and more comprehensive counseling were suggested as ways to improve general knowledge of Norplant, complement and standardize information on the method, and supplement word-of-mouth information, cited by many clients as their main source of family planning information and one of the main reasons they chose Norplant.

The findings from Phase I and Phase II suggest that access to and use of Norplant have continued to increase since the method's introduction in December 1986. Despite the method's disadvantages, including associated side effects and its provider-dependent nature, it was highly appreciated by users for a variety of reasons, particularly its long duration of efficacy and ease of use. Client and provider perspectives suggest that the method has great potential to continue to meet the large unmet need for contraception for both birth spacing and birth limiting in Senegal, including clients with no previous contraceptive experience who comprise half of all new Norplant users from 1986–2000.

To fulfill this potential, several recommendations should be considered to address the gaps in Norplant services in Senegal. The majority of these recommendations were offered by stakeholders themselves at the study's 15 July 2002 dissemination meeting, which was hosted by the Population Council and the Senegal MOH. Specifically, recommendations focused on the following issues: (1) client follow-up, particularly given the predicted increase in the number of clients lost to follow-up by 2003; (2) improved access to Norplant services by making the method more widely available and minimizing unnecessary provider-imposed restrictions to use; and (3) enhancing the quality of Norplant information in the context of method choice for current and potential users by improving counseling and implementing IEC and community outreach campaigns.

Reports of Phase I and Phase II of the study will be made available pending final review.

Implementing Organization(s): Population Council

Collaborating Organization(s): Senegal Ministry of Health

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Latin American and the Caribbean Region

Regional Summary

Work under the Population Council Program III (PCP3) in the Latin America and the Caribbean (LAC) region began as part of the Council's Expanding Contraceptive Choice (ECC) program, supported by a combination of core and field support funds. The ECC program sought to broaden the range and availability of contraceptive options for women and men and to improve the quality of care associated with the provision of contraceptive services. The objective was to develop and implement effective mechanisms for introducing, within national family planning programs, a range of contraceptive technologies that were safe, acceptable to users, programmatically feasible, and that expanded choice in ways consistent with individuals' reproductive health goals. Activities were executed in Brazil, Bolivia, Guatemala, Honduras, and the Dominican Republic, continuing the ECC program of work supported by the previous PCP agreement during 1994–2000. After USAID/Washington discontinued funding for the ECC program, the Council's HIV/AIDS work in Brazil and neighboring countries nevertheless continued. The strong working relationship between Population Council/Brazil staff and USAID/Brazil allowed for the Council's continuing participation in implementing the "strategic approach" to HIV/AIDS services introduction in the Brazil borders region.

Technical Assistance

Much of the ECC program's attention in the LAC region was focused on dissemination activities and providing technical support to health ministries.

Bolivia

Under the PCP3, the ECC program continued providing technical assistance to the Ministry of Health (MOH) for improving family planning programs in Bolivia, focusing on the improvement of quality of care in reproductive health services. In 2001, the Population Council developed a project to expand the implementation of quality of care provided by family planning services in Bolivia. This technical assistance resulted in a very successful project supported by the U.K. Department for International Development and administered by the United Nations Population Fund, which was adopted as an official program by the MOH.

Brazil

Under the PCP3, the ECC program translated *The Essentials of Contraceptive Technology*, a manual on contraceptive technology for family planning providers, from English to Portuguese. The Portuguese version was prepared and published by the USAID-funded Population Information Program of the Center for Communications Programs at the Johns Hopkins School of Public Health, in collaboration with the World Health Organization (WHO) and several other agencies. This translation was widely distributed throughout the country. The ECC program then used the translated material to create a Web site on contraceptive technology for family planning providers that was successfully used by physicians, nurses, and other professionals throughout the country. The Council maintained this Web site for two years, after which the site continued under the direction of Reprolatina, a Brazilian non-governmental organization (NGO).

During 2001 and 2002, the Population Council was an important contributor, collaborating with the Brazil MOH, in adapting the material to establish a plan for national norms in family planning. The plan was published in a manual by the Brazilian Federation of Societies of Obstetrics and Gynecology.

Dominican Republic and Guatemala
The Population Council gave technical assistance to the WHO and the local MOHs in the design and implementation of strategic assessments of issues in reproductive health, with an emphasis in maternal mortality, in the Dominican Republic and Guatemala. The study in the Dominican Republic was integral in shaping the design of the USAID/Brazil country strategy in reproductive health.

Strategic Approach to HIV/AIDS Services Introduction in Brazil's Border Region

In 2001, the USAID Mission in Brazil asked the Population Council to undertake an assessment of the HIV/AIDS epidemic in border areas of the country. In close collaboration with the National STD and AIDS Program of the MOH, the Council prepared an assessment of the situation in six border areas, from Oiapoque, on the border with French Guyana, to Uruguaiana, on the border with Argentina.

This study, co-financed by USAID field support and the Brazil MOH, showed the epidemic was worse in the border areas than in big urban centers, and identified areas for further research. The results were disseminated in a large meeting, with the participation of a wide array of stakeholders from the MOH, NGOs, and donors. The Population Council prepared the final report of the study, which the MOH published and distributed widely, both nationally and internationally.

The study's identification of a series of problems in the border regions prompted USAID and the MOH to create a consortium for HIV/AIDS activities in Brazil, to implement a strategic plan for action research in those areas, with the Population Council designing the research.

Following USAID/Brazil's mandate, the Council also implemented a study in the southern border cities of Foz do Iguaçu and Uruguaiana called "Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment." The study showed that international truck drivers constitute a population that has very limited access to health services, and that they have urgent health needs in addition to those regarding STI/HIV/AIDS. The pre-intervention assessment showed that, with the exception of the Paraguayans, the prevalence of condom use is very high. The intervention consisted of offering information, counseling, and testing for STI/HIV and other preventable diseases within the Customs area. Results on prevalence showed that HIV has a very low prevalence in this group (less than 0.5%), and the prevalence of syphilis was also below the expected rate. The intervention was extremely well accepted, and truck drivers using the services were very happy to have the service because they have no access to services otherwise.

The results of this study were widely disseminated and met with great interest by other institutions that work in the development of HIV/AIDS service projects. The project gained additional visibility after receiving a visit from two U.S. senators and the U.S. ambassador. Accounts of the senators' visits were posted on the USAID/Brazil and U.S. Embassy Web sites.

Additional work undertaken in Brazil included a study in Corumbá, near the border with Bolivia. This study, "Improving the Quality of STI/HIV/AIDS Prevention," was aimed at improving the quality of STI/HIV/AIDS services for vulnerable populations. The study of more than 400 vulnerable people revealed a high STI prevalence but a low HIV prevalence. The most important result was increased access to STI/HIV/AIDS services. The health secretary, understanding the importance of providing these services, is taking measures to sustain their availability after the end of the project.

Conclusion

Projects undertaken by the Population Council in the Latin America and the Caribbean region under the PCP3 were quite successful. Population Council/Brazil was integral in the dissemination of essential reproductive health information and the provision of technical assistance to the Bolivian, Brazilian, and Guatemalan Ministries of Health. In Brazil, the MOH continues to work with Population Council/Brazil, both through the USAID-funded Horizons Program, and under its own funding.

Institutional Support for Regional Professional Societies: Sponsoring a Symposium on Contraceptive Technology at the 17th Meeting of the Latin American Association of Researchers in Human Reproduction

Project Number/s: **03255**
Country/ies: Latin America and the Carribean Region
Technical Coord.: Juan Díaz
Period: April 2001 – May 2001
Objective: To provide institutional support for the ALIRH meeting as part of capacity-building efforts.

Activity Description:

The Population Council's Expanding Contraceptive Choice (ECC) program had a longstanding involvement with regional professional societies, providing them with technical assistance, conducting trainings and workshops, and collaborating on research studies and interventions. Included among these organizations were the Society of Women Against AIDS in Africa; the Latin American Association of Researchers in Human Reproduction (ALIRH), with which ECC was affiliated for many years; and the East, Central, and South African Association of Obstetrical and Gynaecological Societies. As part of efforts to promote cooperation between the international and local family planning and reproductive health communities, and to promote capacity building of local institutions, ECC provided support for a series of seminars and international meetings held by these organizations during Years Two and Three of the Population Council Program III. This activity provided sponsorship of a symposium on contraceptive technologies at ALIRH's 2001 meeting.

Final Report:

The ECC program sponsored a contraceptive technology update symposium at the Latin American Association of Researchers in Human Reproduction's 17th annual meeting in Curitiba, Brazil, held April 27–May 1, 2001. The symposium emphasized emergency contraception and long-acting hormonal methods. Juan Díaz, ECC's medical associate for Latin America and the Caribbean, organized and chaired the symposium, and ECC provided financial support for the participation of four providers involved in the symposium.

Implementing Organization(s): Population Council

Collaborating Organization(s): Latin American Association of Researchers in Human Reproduction (ALIRH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to the Bolivia Ministry of Health

Part of project Number/s: 03200

Country/ies: Bolivia

Technical Coord.: Juan Díaz

Period: 1999 – June 2002

Objective: To provide technical assistance to the Bolivia Ministry of Health (MOH) to improve the overall quality of family planning and reproductive health services.

Final Report:

Since 1999 the Population Council's Expanding Contraceptive Choice (ECC) project has provided technical assistance to the Bolivia MOH for developing strategies to improve the quality of the country's family planning and reproductive health services. Beginning in June 2001, this technical assistance has focused on a project to improve the quality of care provided by family planning services in nine key municipalities. This project (funded by the UK Department for International Development and UNFPA, and administered by UNFPA and the Bolivia MOH) is a Stage II intervention based on WHO's Contraceptive Strategic Assessment Framework. The project is closely connected to the REPROLATINA project and other UNFPA projects so that staff on these projects can coordinate activities and share experiences and lessons learned.

Since project inception, activities have been initiated in four of the nine municipalities: El Alto in the department of La Paz; Warnes and Distrito 5 in the department of Santa Cruz; and Distrito Urbano in the department of Cochabamba. In these municipalities, initial diagnostic assessment and provider training have been conducted, and site supervision is ongoing. In the municipalities of Tarija and Oruro, initial assessment and personnel training began in May 2002 (and ended in July 2002). In all nine municipalities, efforts to improve community participation are planned. Executive committees will be established and policy dialogues will be implemented to supports these efforts.

Because the ECC project has been terminated, technical assistance to the Bolivia MOH will no longer be provided under the auspices of this program after Year Three of the Population Council Program III.

Implementing Organization(s): Population Council

Collaborating Organization(s): Bolivia Ministry of Health
UK Department for International Development
United Nations Population Fund

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to Update National Family Planning Guidelines in Brazil

Part of project Number/s: **03200**

Country/ies: Brazil

Technical Coord.: Juan Díaz

Period: Ongoing –June 2002

Objective: To provide technical assistance to the Brazil Ministry of Health (MOH) to update and revise the national family planning guidelines.

Final Report:

Efforts have been made to incorporate the technical content of Brazil's national family planning guidelines into existing training programs, educational curricula, and so forth. Staff in the Population Council's Expanding Contraceptive Choice (ECC) project have played an ongoing role in these efforts, on both consultative and programmatic levels. A contraceptive technology Web site for providers, created by ECC staff in collaboration with the Brazilian Federation of Societies of Gynecology and Obstetrics and the University of Campinas, is one example of a project undertaken to help the Brazil MOH achieve its goals (see "Contraceptive Technology Internet Web Site for Providers in Brazil: Continued Operation and Maintenance").

During Year Two of the Population Council Program III, a disagreement arose within the Brazil MOH concerning inclusion of a section on sexually transmitted infections, including HIV infection and AIDS, in the national family planning guidelines. The MOH was unable to resolve this disagreement, which halted the finalization and printing of the guidelines. As a result, ECC staff were unable to pursue this activity during Year Three.

Because the ECC project has been terminated, technical assistance to the Brazil MOH will no longer be provided under the auspices of this program after Year Three.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazil Ministry of Health

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

The Essentials of Contraceptive Technology—Translation from English to Brazilian Portuguese

Project Number/s: **03221**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: April 1999 – March 2002
Objective: To translate, publish, and disseminate a Portuguese-language version of The Essentials of Contraceptive Technology.

Final Report:

Brazil has been engaged in an ongoing effort to improve its reproductive health/family planning program and to train and update physicians and other health workers. The Essentials of Contraceptive Technology, published by the Johns Hopkins Population Information Program (PIP), is a useful and reliable source of updated information for family planning and other providers. Previously, this resource was available only in English. Those who have used the English version of this publication insisted that a Portuguese-language version was needed for the majority of Brazilian providers who do not speak English and that it would be useful for medical and nursing students as well.

Under the previous Population Council Program, CCP-A-00-99-00013, Population Council staff in the Expanding Contraceptive Choice (ECC) project, with assistance from the Johns Hopkins PIP and the USAID Office of Population, translated a recently updated version of The Essentials of Contraceptive Technology into Brazilian Portuguese. The plan was to publish and distribute the book to providers nationwide in Brazil. By September 2000 a full editorial review of the publication had not yet been completed; therefore, work continued under the Population Council Program III to complete publication and distribution of the book. During Year Two the editorial review revealed translation errors, and a further review of the contraceptive methods included in the book was felt to be necessary. In early 2001, the revised manuscript was sent to Johns Hopkins for final formatting and layout, with an eye to making the publication consistent with the English-language version of the book. A wall chart of information presented in the book, written in Brazilian Portuguese, was published; copies were shipped to Brazil in February 2001.

In Year Three Johns Hopkins University Press printed more than 50,000 copies of the Brazilian Portuguese version of book. These were shipped to Brazil in November 2001 for distribution, along with 20,000 copies of the wall chart. Unfortunately, the shipment was held up by a long Customs delay and was not released until mid-January 2002. The books were subsequently distributed to the Brazilian Federation of Societies of Gynecology and Obstetrics (FEBRASGO), nongovernmental organizations, universities, Secretariats of Health, and health professionals. FEBRASGO distributed the majority of the books. Distribution was completed at the end of March 2002. So far, very positive feedback has been received from the scientific and service-delivery communities regarding the quality and usefulness of the publication.

Collaborating Organization(s): Brazilian Federation of Societies of Gynecology and Obstetrics
Johns Hopkins Population Information Program
USAID Office of Population

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Contraceptive Technology Internet Web Site for Providers in Brazil: Continued Operation and Maintenance

Project Number/s: **03222**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: February 2001 – March 2002
Objective: To maintain and upgrade a Web site on contraceptive technology and related issues for providers in Brazil.

Final Report:

A 1993 WHO assessment in Brazil revealed that most family planning providers were not adequately informed about changing contraceptive technologies. The Brazil Ministry of Health (MOH) agreed that its norms and guidelines were out of date because of the nature of traditional publishing. To overcome these obstacles, Population Council staff in the Expanding Contraceptive Choice (ECC) project developed, in collaboration with the University of Campinas (CEMICAMP) and the Brazilian Federation of Societies of Gynecology and Obstetrics (FEBRASGO), an interactive, Portuguese-language Web site on contraceptive technologies (http://www.anticoncepcao.org.br/). The site was developed under the previous Population Council Program CCP-A-00-99-00013 with the support of USAID/Brazil. Launched in 2000, the site provides useful information on various issues related to contraceptive technology; key articles for policymakers, physicians, and other providers; a question-and-answer section; and links to the Brazil MOH Web site and the sites of other relevant scientific societies and organizations. Efforts have been made to encourage periodic discussions and debates on current issues related to reproductive health and contraception. During Year Two a number of key indicators were measured as part of an ongoing assessment of the Web site, including the number of visits to the site, the level of participation in debates and discussions, and the number of subscribers to the site. A breakdown of these variables was compiled in February 2001.

During Year Three the Web site was updated every two months. A new feature was added that allows a version of the site to be downloaded and printed easily by users. In July 2001 a statistical report was generated by the host server, providing data on the number of visits to the site (home page and subsequent pages), along with other relevant data. The report showed, as expected, that most users of the site were located in Brazil, with a much smaller number of users in the United States. By the end of Year Three, the Web site was receiving more than 10,000 visits per month.

Population Council Program III funding kept the Web site operational through the end of March 2002, when support to maintain the site was secured through the REPROLATINA project and from the Bill & Melinda Gates Foundation. (Beginning in 2003, the site will be maintained exclusively with Gates Foundation funding.)

Implementing Organization(s): Population Council
Collaborating Organization(s): Brazilian Federation of Societies of Gynecology and Obstetrics
Reprolatina
University of Campinas

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Stage 1

Project Number/s: **03257**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: April 2001 – September 2002
Objective: To acquire better knowledge of the factors that influence transmission of STIs/HIV and, in turn, learn how to reduce transmission in municipalities in the border regions of Brazil.

Activity Description:

Although some work has been done to understand STI/HIV transmission patterns in the more populous regions of Brazil along the coast and throughout the northeast region, little information is available regarding transmission along the 15,000 square kilometers of Brazilian territory bordering other South American countries. The little research that has been done indicates that HIV/AIDS is spreading from more urban and affluent areas of the country to rural and poorer sections, such as the border regions, but the pace of this spread and its effect on prevalence are not known. In addition, the border regions possess very poor medical services and are vulnerable to a number of high-risk factors contributing to transmission, such as trafficking of sex workers, drugs, and other contraband. This Stage 1 assessment based on WHO's Contraceptive Strategic Assessment Framework has been adapted to explore the issue of STI/HIV transmission and unwanted pregnancy prevention in the border regions. It combines qualitative and quantitative research methods to assess the cultural context of STI/HIV transmission and service delivery in order to determine strategies for prevention, including dual protection. The assessment takes place in six municipalities of Brazil on the borders of other South American countries: Foz do Iguaçu, on the border of Argentina and Paraguay; Uruguaiana, on the border of Argentina and Uruguay; Corumbá and Guajará-Mirim, on the border of Bolivia; Tabatinga, on the border of Colombia and Peru; and Oiapoque, on the border of French Guiana. Study findings will be used to improve the quality of service delivery in the border regions and to develop a plan of action for effective and efficient strategies to prevent STIs/HIV and unwanted pregnancy. The final report of the Stage 1 assessment will be published as a bulletin of the Brazil Ministry of Health (MOH), distributed throughout the country, and included on the MOH's Internet Web site.

Final Report:

Study preparations commenced in the second trimester of 2001, including the finalization of the study protocol, the elaboration of the background paper, the completion of a stakeholders meeting, the training of the fieldwork team, and establishment of contact with representatives from the study locations.

In August 2001, the Council hosted a stakeholder's workshop at which the perspectives of policymakers, program managers, service providers, educators, and research groups were obtained and consensus on the project's strategic direction was formulated. In September the data collection team was trained by Margarita Diaz and Francisco Cabral from the NGO Reprolatina. Fieldwork began in October and was completed by December 2001. Six sites were visited by teams of 6–8 researchers for a minimum of five days of data collection at each site.

In March 2002, a meeting was held with the MOH, USAID representatives, and members of the data collection team to discuss results of the fieldwork and prepare the outline of the final report, which was

published in July. The final dissemination workshop, AIDS at the Frontiers: Collaborative Project, was held 6–8 May 2002 at the Carlton Hotel in Brasilia. Over 70 people attended, including representatives from the municipalities and states included in the study, representatives from the MOH, and staff from national and international NGOs, agencies, and donors. Study findings include the following: (1) Severe deficiencies of quality and access were detected in health services in all the places studied, as well as a complete lack of integration of thematic content (such as dual protection) between services. (2) Deficiencies are greater in the area of prevention than in testing and treatment. (3) Limitations are more pronounced in the sites in northern Brazil, where HIV/AIDS programs have been only partially implemented and providers are few. (4) Frontier areas present specific environments that aggravate deficiencies (e.g., undocumented populations, illegal trade, drugs, and prostitution); these environmental issues must be incorporated into the design of future interventions and considered in discussions of health and development policies at the border. (5) The MOH has not yet developed a political position or systematic course of action to deal with the spread of HIV/AIDS in the border regions.

Based on analyses of the findings, discussions within the Population Council, and the proceedings of the dissemination seminar, the following recommendations can be made: (1) The National AIDS Program, in conjunction with the MOH must define and implement a national borders strategy to combat the spread of HIV. (2) Development of such a strategy necessitates a more effective implementation of existing international accords and the elaboration of new means of international cooperation, which explicitly prioritizes HIV/AIDS. (3) STI/HIV/AIDS prevention activities should prioritize commercial sex workers, truck drivers, adolescents, the incarcerated population, and other marginalized and mobile populations in future programs at frontier areas. (4) HIV prevention efforts must be integrated into the health system, including reproductive health and family health programs. (5) NGOs and social mobilization are key to stemming the spread of HIV and procuring human rights for all; partnerships with community-based organizations and NGOs should be sought and fortified in collaborative efforts in the STI/HIV/AIDS field. (6) Research must be encouraged and supported to shed light on the current situation and best practices for effecting change. The MOH has stated that it will continue to support the Council in implementing applied research aimed at resolving some of the problems detected (i.e., projected USAID Mission–financed projects to improve access to prevention, testing, and treatment of sex workers in Corumbá and Uruguaiana and truckers in Foz do Iguaçu).

Galley proofs of the final report have been submitted to the MOH, but because of administrative delays there, the report has not yet been published and distributed. Publication is expected to take place in October 2003. Once the final report is published, papers will be prepared for submission to English- and Portuguese-language journals.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazil Ministry of Health—National Coordination on STI/AIDS
Reprolatina

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Project Development Stage

Project Number/s: **03264**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: June 2002 – December 2002
Objective: To facilitate the transition between Stages 1 and 2 of the project Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions.

Activity Description:

Stage 1 of the project Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions was completed in September 2002. At that time, proposals for three follow-up activities were developed for Stage 2 of the strategic assessment. These proposals were presented to USAID/Brazil, which agreed to fund two of them; the third will be supported by non-USAID funding. A transition phase is necessary to support personnel, travel, meetings, and supplies needed for the full development of the three projects. This project development stage was conducted by a senior researcher who was an integral part of the Stage 1 assessment and a senior epidemiologist who designed the methodology and decided on the sample size, with short-term assistance from a research intern, an administrator, and a secretary.

Final Report:

During Year Four of the Population Council Program III, two project proposals were developed for Stage 2 of the project Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions (see "Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez, and Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu [Paraná State] and Uruguaiana [Rio Grande do Sul State]"). The proposals were sent to the Council's Institutional Review Board and were subsequently approved. Project staff visited the field sites and began the process of selecting and hiring the local personnel who will coordinate the projects. During October–December 2002, formative research was undertaken to define research instruments and the contents of information, education, and communication materials.

Also during Year Four research results from the Stage I assessment were presented at the XIV International AIDS Conference in Barcelona, Spain, the First Pan-Amazonian Congress on STDs in Manaus, Brazil, and the Fourth Congress of the Brazilian Society of Sexually Transmitted Diseases in Manaus.

In addition to local planning meetings held in Corumbá and Foz do Iguaçu, five meetings were held with the Ministry of Health in Brasilia, including meetings with the general director of the STD/AIDS program and staff members of the Department of Prevention and Diagnosis and the national directorate of the STD/AIDS program regarding Stage 2 implementation.

Implementing Organization(s): Population Council
Collaborating Organization(s): AIDS Solidarity Action Network (NASA)
Brazil Ministry of Health—National Coordination on STI/AIDS
DKT
Organization of Citizenship, Culture, and the Environment (OCCA)
Pathfinder International

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez

Project Number/s: **05826**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: November 2002 – August 2005
Objective: To reduce the risk of STI/HIV/AIDS transmission among vulnerable populations in Corumbá and the neighboring Bolivian municipality through education aimed at decreasing risk behaviors by increasing the adoption of consistent condom use and through service provision aimed at increasing testing and treatment for sexually transmitted infections (STIs).

Activity Description:

In late 2000, the Brazil Ministry of Health, concerned about the growing number of HIV infections and insufficient HIV/AIDS services in the border regions of the country, proposed a collaboration with the Council to perform an assessment of HIV/AIDS in Brazil's border regions. The study, "Strategic Assessment of STI/HIV Transmission in the Border Regions of Brazil: Stage 1," May 2001–June 2002, was an assessment based on WHO's Contraceptive Strategic Assessment Framework, which was adapted to explore the cultural context of STI and HIV transmission and the service delivery system in six border municipalities to develop strategies for improving prevention, diagnosis, and treatment. Results showed that these regions are indeed lacking in STI/HIV/AIDS services and prevention programs, and the need for these services and programs was especially prominent in marginalized populations.

One of the municipalities included in the assessment was Corumbá, a region in western Brazil that shares a river border with the Bolivian municipality of Puerto Suárez. Corumbá is a relatively small town with a large floating population. Many are attracted to Corumbá by the availability of cheap drugs (drug use has had a profound effect on the AIDS epidemic in Corumbá); additionally, the fishing and eco-tourism industries attract 75,000 tourists each year. Together, these characteristics have stimulated a parallel growth in sex commerce. Despite the proliferation of the commercial sex industry, the current municipal AIDS program has few resources to expand actions that target commercial sex workers, whose activities cross the border into Bolivia, where there are no STI/HIV-related services at all.

This three-year project, one of three comprising Stage 2 of the Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions, seeks to reduce the risk of STI/HIV/AIDS transmission among high-risk populations both in Corumbá and in the neighboring Bolivian municipality by decreasing risk behaviors through the adoption of consistent condom use. The strategy includes four basic components: availability of free condoms; condom promotion both where commercial sex work occurs and in other areas; improved access to voluntary counseling, testing, and treatment for STIs; and monitoring and treatment of the HIV-positive population.

Final Report:

This project sought to assess the frequency of STIs and reduce the risk of STI/HIV/AIDS transmission in Corumbá and Puerto Suárez, the neighboring Bolivian municipality, among high-risk populations, and especially among sex workers. It aimed to decrease risk behaviors by increasing the consistent use of condoms. Additionally, the objective was to evaluate the influence of an intervention aimed at increasing vulnerable populations' knowledge of STI/HIV/AIDS transmission.

The project activities were twofold: a) educational activities in the community aimed at improving a sense of self-efficacy of the population, promoting preventive behaviors, and communicating an improvement in available services; and b) implementation of quality services offering participation in a research project to evaluate the prevalence of STIs and to assess the effect of the above-mentioned interventions on STI prevalence. All women were informed that they would receive high quality care irrespective of their participation in the research study.

The results regarding the first group of activities were impressive. The volunteers who provided the community with STI/HIV/AIDS education were well trained and motivated, and they were able to establish a good rapport with the target population, thereby gaining their confidence and acting as effective counselors. As a consequence, the target population began to seek out their expertise, asking for advice and requesting to participate in the study. The service providers were also well trained and provided high quality and attentive care to the women which resulted in stricter adherence to the study protocol. Many women expressed that this was the first time in their lives that they had been treated as a human being. Because of this rapport and quality of service, a large proportion of the sex worker population came to receive services and enroll in the study: of the estimated 600 sex workers in the area, 420 participated in the study. However, follow-up was lower than anticipated due to the very high mobility of this population.

The analyzed data show that the combined STI prevalence for Chlamydia and gonorrhea decreased over time. The prevalence of Chlamydia was 14.7% in the first visits and decreased to 5.2% in the fourth visits, and for gonorrhea, it was 4.4% in the first visits and 2.3% in the fourth visits. The research also aimed to identify the most important variables influencing the adoption of risky behaviors and thus the prevalence of STIs. The data are still being analyzed. Results are pending analysis of the data.

Despite the fact that sex workers' use of condoms with occasional clients was very high at the beginning of the study and was not significantly changed by the interventions, the use of condoms with frequent clients and partners increased significantly. The qualitative evaluation, which has not yet been completed, appears to confirm the initial impression that women were delighted by the quality of services, and that they would continue to use them if offered after the end of the project.

This project gained the support and respect of members of the Secretary of Health, who had initially not seen its utility. In fact, members of the Secretary of Health are now the most enthusiastic promoters of the project, and financial support has been secured to continue the project's activities past the completion of the PCP3 Cooperative Agreement.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazil Ministry of Health—National Coordination on STI/AIDS
Municipal Health Secretary of Corumbá
Pathfinder International
Rede Brasileira de Profissionais do Sexo

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State)

Project Number/s: **05827**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: December 2002 – August 2005
Objective: To reduce risk behaviors and STI/HIV transmission among border-crossing truck drivers by improving access to condoms, testing services, and prevention information, and to determine the effectiveness of a marketing and voluntary counseling and testing (VCT) campaign for HIV prevention in this population; to design a logistics system to guarantee high-quality health treatment for HIV-positive truck drivers.

Activity Description:

In late 2000, the Brazil Ministry of Health, concerned about the growing number of HIV infections and insufficient HIV/AIDS services in the border regions of Brazil, proposed a collaboration with the Population Council to perform an assessment of HIV/AIDS in the border regions. The study ("Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Stage 1," May 2001–June 2002) was a Stage 1 assessment based on WHO's Contraceptive Strategic Assessment Framework.

Two southern municipalities participated in the assessment: Foz do Iguaçu, which shares a border with Argentina and Paraguay, and Uruguaiana, which shares a border with Argentina and Uruguay. Assessment findings in both Foz do Iguaçu and Uruguaiana documented an enormous amount of movement of goods and people across the borders and revealed that the extremely mobile population of truck drivers who cross the highly-traveled southern borders of Brazil have little to no access to HIV/AIDS prevention, testing, and treatment services. Because of the mobile nature of their profession, which lends itself to exposure to prostitution, truck drivers are a vulnerable group for STI/HIV/AIDS infection and a bridge population for the spread of STIs/HIV.

This three-and-a-half-year project seeks to learn more about perceptions of HIV and risk behaviors in this vulnerable population; to arm truck drivers with improved access to information, testing, and counseling services; to increase their knowledge of their HIV status, mechanisms of STI/HIV/AIDS prevention, and their risk; and, ultimately, to increase the frequency of consistent condom use.

Final Report:

The initial activity of this project was a baseline diagnostic assessment aimed at identifying the social and economic characteristics of truck drivers in Foz do Iguaçu and Uruguaiana, and at identifying in this group the perceptions of HIV and risk behaviors related to increased risk of transmission of HIV/AIDS. 1,775 truck drivers were interviewed — 779 in Foz do Iguaçu, and 996 in Uruguaiana. The results of the baseline assessment showed that truck drivers who do not have access to health services feel marginalized and stigmatized for being characterized as vectors of infections. A significant minority of the truckers reported having sex while on the road, and the frequency of this activity appears to be related to trip length and to total time away from their hometown. Most of the truckers use condoms when having occasional sex. Paraguayans appear have the highest proportion of inconsistent use or non-use of condoms. The results from Foz do Iguaçu and Uruguaiana were not significantly different in most variables.

The intervention involved offering free condoms, education, and VCT services for HIV and syphilis from a medical trailer stationed in the customs area of Foz do Iguaçu, to truck drivers who passed through the customs area. In addition, the group offered education and counseling on other health topics such as nutrition and how to control high blood pressure and glucose levels. Over the duration of the study, 2,304 truck drivers were tested for HIV and syphilis. The prevalence of HIV was lower than that found in pregnant women (5/2,304=0.22%). Educational activities reached more than 5,000 truck drivers and more than 1,000 of the truckers asked about other health issues or simply sought advice without being tested for HIV and syphilis.

Qualitative evaluation showed that truck drivers found the services very useful, and their only complaint was that other preventive health services, such as ophthalmology and dental services, were not also available.

After the intervention, the evaluation was repeated using a questionnaire similar to the one used in the baseline study (but without questions which had been qualified as not useful in the baseline survey and with the modification of some questions to make them more understandable). In this evaluation we interviewed 2,400 truck drivers (1,203 in Foz do Iguaçu and 1,197 in Uruguaiana); results are not yet available. Recruitment for this evaluation was easier than for the baseline survey because very few truckers refused to participate. In fact, many truckers who had not been randomly selected to participate in the evaluation wanted to, and, unprompted, many of them asked for continuation of the services. The results did not confirm the expected high HIV prevalence in this group but did show that truck drivers comprise a group that is in great need of assistance because of very limited access to health services.

After the end of the PCP3, this activity will continue under the Horizons Cooperative Agreement. When Horizons support ends in December 2005, Uniamerica, a University in Foz do Iguaçu, will continue to offer services. The Population Council has offered to leave the trailer in the customs area, and the customs area administration will continue to provide support for the trailer in the form of electricity, water, cleaning, and maintenance. The University will provide personnel and students to maintain and possibly to even increase services. Ensuring sustainability of services was one of the most important achievements of the project. This activity demonstrated that the provision of services was very useful to this marginalized population, and several municipalities, including Uruguaiana, are now trying to build on this success by replicating this project.

Implementing Organization(s): Population Council

Collaborating Organization(s): AIDS Solidarity Action Network (NASA)
Brazil Ministry of Health—National Coordination on STI/AIDS
Brazilian Truck Drivers' Union
DKT
Municipal Health Secretary of Foz do Iguaçu

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Technical Assistance for the Implementation of the USAID Brazil Research Strategy on STI/HIV/AIDS in Brazil

Project Number/s: **44804**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: April 2004 – June 2005
Objective: Provide technical assistance for the development and implementation of the research strategy of the USAID/MOH Consortium

Activity Description:

This technical assistance project will consist of the following objectives:

1. Collaboration on proposal preparation, including writing the methodology section and reviewing all other sections, for a study replicating a Council-designed project offering education, voluntary counseling and testing (VCT) for HIV/AIDS and STIs, as well as general health prevention actions, to truck drivers passing through customs areas on the borders of Brazil (see "Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu [Paraná State] and Uruguaiana [Rio Grande do Sul State]").
2. Collaboration on the preparation of the research instruments for the baseline assessment, including an adaptation of the questionnaires and other research instruments used in the Foz do Iguaçu project. The research instruments for the baseline assessment will combine the most successful elements of questionnaires used in the Foz do Iguaçu project with those from questionnaires developed by BEMFAM for use with the truck driver population. The instruments for VCT and clinic records from the Foz do Iguaçu project will be used, with minor modifications.
3. Training of the research team. The staff working in Foz do Iguaçu has extensive experience in training and will be in charge of this aspect of the project in collaboration with the Ministry of Health (MOH). The Population Council will train the field workers and will monitor data collection and the other field activities.
4. Supervision and monitoring. Juan Díaz, principal investigator, and Cristina Ogura, local coordinator of the project in Foz do Iguaçu, will work to ensure project procedures are followed.
5. The Population Council will work together with BEMFAM in the evaluation of the project and writing of the report and publications.

Final Report:

Population Council staff in Brazil collaborated with the Sociedade Civil Bem-Estar Familiar (BEMFAM) in the implementation of the HIV/AIDS research strategy developed by the USAID/MOH Consortium in Brazil. As part of the strategy, it was decided to implement a study with truck drivers in Uberlandia. The data from this study would be compared with the data obtained from the mission-funded truck drivers project in Foz do Iguaçu and Uruguaiana, "Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State)."

Preparation for the study was initiated in April 2004. However, approval by the National Ethical Committee took longer than expected due to administrative delays with the MOH. Formative research included meetings with local authorities and representatives of the truck driver community. In addition, visits were made to NGOs in Uberlandia and neighboring cities seeking possible collaborators for the study

as well as for future partnerships. We had several meetings to discuss the methodology and the research instruments that had been adapted from the study in Foz do Iguaçu and Uruguaiana and the separate study initiated by BEMFAM. Based on the results of previous studies, special care was taken make the questions sensitive to stigma and discrimination. In addition to studying the truck drivers, we included a sample of 100 female and 100 transvestite sex workers, located in the same area as the truck drivers. The questionnaires were pre-tested and validated with truckers and sex workers in the same city and final versions of the instruments were prepared.

Before initiating the fieldwork, the Population Council and BEMFAM organized a stakeholders meeting with local authorities and representatives of the truck drivers, health providers, and sex workers. We used the opportunity to highlight the importance of working with truck drivers, not only on STI/HIV/AIDS issues, but also on preventative health issues and social dimensions of health such as discrimination. After training the team, the field work ran smoothly from October 2004 until the end of January 2005. Truck drivers and sex workers were easily and rapidly recruited and there was a very low rate of refusal to participate in the study. In contrast, the group of transvestites was difficult to reach and a slightly higher rate refused participation.

Data entry and cleaning was finished in May 2005. Statistical analysis is currently in the final stage and the final report will be available at the beginning of 2006. We are planning a dissemination meeting in Uberlandia to present the results to the Municipal and State health authorities. Together with BEMFAM, we plan to publish peer reviewed articles which focus on the issues of stigma and discrimination, based on the combined data from the previous study in Foz do Iguaçu and Uruguaiana and this baseline assessment.

Implementing Organization(s): Population Council

Collaborating Organization(s): BEMFAM
Brazil Ministry of Health—National Coordination on STI/AIDS

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Technical Assistance to Improve the Knowledge and Use of STI/HIV/AIDS Related Services in Vulnerable Groups in Brazil

Project Number/s: **44805**
Country/ies: Brazil
Technical Coord.: Juan Díaz
Period: November 2004 – August 2005
Objective: Provide technical assistance to support the implementation of baseline studies in vulnerable male populations and to build the research capacity of local NGOs in selected sites in the South and Southeastern regions of Brazil.

Activity Description:

In order to implement the USAID Research Strategy in Brazil, USAID and the Brazil Ministry of Health's (MOH) National STI/HIV/AIDS Program created a Consortium for the development of a joint research strategy, and invited the Population Council to be the executive agency for the implementation of this strategy. The goal of the research strategy is to have accurate and reliable information on which to base future activities focused on preventing HIV infection in highly vulnerable groups. The first meetings were devoted to defining priorities, and it was decided that the research activities would focus on improving the knowledge of STI/HIV/AIDS prevalence, sexual behavior, and other potential risk behaviors in highly vulnerable groups and on improving the access to and use of STI/HIV/AIDS-related services in these populations. Based on the MOH's suggestion, it was decided to initiate implementation of the strategy by undertaking studies to define the HIV prevalence in vulnerable male populations and the primary behaviors that could explain the high HIV prevalence in these groups.

Population Council staff will provide technical assistance to the USAID Mission in Brazil and to the MOH's National Project for STI/HIV/AIDS to implement this combined USAID/MOH research strategy. The primary result of this technical assistance will be the preparation of this research project and completion of the implementation of the Geographic Information System, which will help determine the situation of the epidemics in the Southern and Southeastern regions of Brazil. Additionally, personnel will be trained to undertake the research projects, and the research capacity of local NGOs will be developed in selected sites in the South and Southeastern regions of the country.

Final Report:

After analyzing the cost effectiveness of different approaches, the Consortium decided to undertake a study of men who have sex with men (MSM). The following year, research would continue with studies focusing on male sex workers and transvestites.

As part of the new strategy approved by the MOH, all research projects should be reviewed and approved by the Centers for Disease Control and Prevention (CDC) before being officially approved. Council staff initiated the preparation of the proposals for the studies in collaboration with the MOH. Inclusion of the CDC in this process was important for improving the quality of the proposal; their expertise in defining the sample procedures was especially valuable.

While preparing the proposal, the Council discussed with the partners the best location for the study and it was decided to perform the study in Campinas, in collaboration with the Municipal Secretary of Health. Campinas was chosen as the study site because of the successful previous collaborations with the

Municipal AIDS program and the quality of support services in Campinas. Additionally, since the Population Council office is located in Campinas, study monitoring would be greatly facilitated by the selection of Campinas as the study site, a particular asset since the sampling methodology has not been previously used with an MSM population.

As part of the efforts to train personnel in undertaking the research projects, the preparation of the proposal included a course on Respondent Driven sampling, which is utilized in the study.

After the proposal was approved by the Population Council IRB and by the National Committee on Ethics in Research (CONEP), we defined the study initiation in October, two months after solving the methodological problems. This study will be the first to be implemented under the USAID/MOH Consortium strategy.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazil Ministry of Health
Brazil Ministry of Health—National STI/HIV/AIDS Program
Municipal Health Secretary of Campinas

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Strategic Assessment of Reproductive Health Services in the Dominican Republic

Project Number/s: **03259**
Country/ies: Dominican Republic
Technical Coord.: Juan Díaz, Suellen Miller
Period: August 2001 – June 2002
Objective: To assist the Dominican Republic Ministry of Health (MOH) and the country's USAID Mission in developing a five-year reproductive health strategy by conducting a reproductive health needs assessment, including identifying and prioritizing problems and developing strategies to solve these problems.

Final Report:

The Dominican Republic is in the midst of economic, social, and health changes that began in the 1970s—changes that directly and indirectly affect the reproductive health of the island's citizens. According to a study conducted by the Population Council's Expanding Contraceptive Choice (ECC) project, over 60 percent of married women in the country use modern contraceptives, and 99.9 percent of women know of some contraceptive method. Nevertheless, there remain significant reproductive health problems requiring attention.

In the spring of 2001, ECC staff were invited by the Dominican Republic MOH and the local USAID Mission to discuss the current status of reproductive health in the country and to plan for a proposed Norplant®-to-Jadelle® transition study. During this visit, concerns about several reproductive health-related issues were raised. Low use of birth-spacing methods was contributing to high levels of early and closely spaced births, preventing many women from leaving home to pursue their education or participate in the workforce. Surgical sterilization was widespread; but whether this was a result of client preference, lack of contraceptive options, provider bias, or other unidentified factors was unclear. Use of effective contraception among sexually active adolescents was low, contributing to high rates of adolescent pregnancy and maternal mortality. The country's maternal mortality rate (MMR) was unacceptably high (approximately 130–144/100,000), despite high levels of institutional delivery (92–97 percent) and antenatal care. Nearly one-third of these deaths were attributed to toxemia; the extent to which HIV infection/AIDS contributed to the MMR was unknown. ECC staff were asked to provide technical assistance and team leadership on a Stage 1 reproductive health needs assessment guided by WHO's Contraceptive Strategic Assessment Framework, supported by funding from the USAID Mission.

In the fall of 2001, a team of Council consultants attended a stakeholders' meeting to prioritize reproductive health problems in the country. In November 2001, the assessment team met to train in using the WHO assessment strategy methodology and to select sites for the assessment. In November and December 2001, the team visited the sites—Barahona Province, San Francisco de Marcoris, and the National District—to interview decisionmakers, providers, and users; observe clinical procedures in both inpatient and outpatient reproductive health facilities; conduct focus groups with service users and providers; and inspect facilities and their records. The assessment team then returned to Santo Domingo and met for three weeks to discuss and synthesize the results of their research.

Results of the needs assessment confirmed many assumptions and beliefs held by policymakers, researchers, providers, users, and health activists regarding the status and causes of reproductive health problems in the country. These problems were long-standing and largely interrelated. For example, lack of

access to a range of reversible contraceptives and dual-protection methods, particularly by adolescents and poor/poorly educated women, contributed to high rates of adolescent pregnancy and maternal mortality, as well as to a high rate of unwanted pregnancy leading to abortion and to increasing rates of sexually transmitted infections, including HIV infection. These problems reflect deficiencies and gaps in the country's reproductive health system, including inadequate access to and quality of reproductive health services and insufficient coverage of all sectors of the population in need of services. Cultural, religious, economic, and social factors; a lack of political will; nonadherence to new health norms; and slow introduction of health-sector reforms have all contributed to these problems. Because the indicators of poor reproductive health are highest among adolescents and poor women, recommendations based on the needs assessment largely call for public-sector changes.

A preliminary report of the needs assessment was presented at a stakeholders' meeting in late January 2002, where recommendations based on the report were developed. In April 2002, ECC staff returned to the Dominican Republic to help USAID Mission staff assess two possible sites for follow-up interventions: Cibao and Higuey. A final report of the needs assessment, detailing study results and recommendations, is being edited, translated into Spanish, and prepared for distribution. The report will be used to assist the Dominican Republic MOH and the USAID Mission in developing a five-year-strategy to improve the country's reproductive health services.

Implementing Organization(s): Population Council

Collaborating Organization(s): Dominican Association for the Well-Being of the Family (PROFAMILIA)
Dominican Republic Ministry of Health
EngenderHealth
INTRAH/PRIME II
John Snow, Inc.
Program for Appropriate Technology in Health
REDSALUD

Activity Funding: MAARD

Contribution to Results Framework: IR 1.2

Technical Assistance for a Preintroduction Study of Norplant® in Guatemala

Part of project Number/s: **03200**

Country/ies: Guatemala

Technical Coord.: Juan Díaz, Suellen Miller

Period: October 1999 – September 2001

Objective: To assess the demand for and acceptability of Norplant among Guatemalan women and to develop a profile of women who select this method.

Final Report:

The Population Council collaborated with the Guatemala Social Security Institute (IGSS) and the Guatemala Association for the Well-Being of the Family (APROFAM), the local International Planned Parenthood Federation affiliate, to conduct this Norplant study. The study assessed the demand for and acceptability of this method, continuation and failure rates, and user satisfaction; it developed a profile of women who select the method; and it included a willingness-to-pay component to help determine whether APROFAM could charge for the method. The study was conducted in four clinics in Guatemala City (among urban and periurban women) and in one clinic in the province of Quezaltenango (among rural Mayan women). While the project was not funded by the Council's Expanding Contraceptive Choice (ECC) project, Juan Díaz, the ECC medical associate for Latin America and the Caribbean, provided technical assistance.

Activities commenced in October 1999. The first three months were spent finalizing research instruments/materials and training physicians and counselors to provide Norplant implants. In 2000 approximately 35 counselors and nurses were trained by two expert counselors from the Instituto Chileno de Medicina Reproductiva (ICMER). Because of the high demand for Norplant in all the clinics, it was necessary to train eight additional doctors. Study participants began receiving Norplant implants in all five clinics in January 2000. Over the following six months, the method was accepted by 1,187 women, with only six requesting removal. Acceptance rates continued to increase. During the first half of 2001, data were collected and tabulated; meetings were held to define future activities once the project ended; and researchers investigated possibilities for purchasing Norplant from sources other than those from which USAID procured the implants. As of 30 June 2001, 4,413 Norplant insertions were done in IGSS and APROFAM clinics.

Altogether, during the 21-month intervention period (1 January 2000–30 September 2001), a total of 5,161 Norplant insertions were done. Total extractions numbered 412, representing 8 percent of insertions. Continuation rates were estimated at 93 percent at six months; 86 percent at 12 months; and 77 percent at 18 months. These rates are consistent with international standards, which have estimated a continuation rate of 84 percent at 12 months. Primary reasons given for discontinuation were irregular bleeding, headache, breast pain, and partner objection.

Implementing Organization(s): Population Council

Collaborating Organization(s): Guatemala Association for the Well-Being of the Family
IGSS (Instituto Guatemalteco de Seguridad Social)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to the Guatemala Ministry of Health to Develop a Reproductive Health Needs Assessment Strategy

Part of project Number/s: **03200**
Country/ies: Guatemala
Technical Coord.: Juan Díaz
Period: July 2001 – June 2002
Objective: To provide technical assistance to the Guatemala Ministry of Health (MOH) to develop a reproductive health needs assessment strategy.

Final Report:

Ever since WHO developed its strategy for contraceptive introduction, the Population Council's Expanding Contraceptive Choice (ECC) project was involved in its implementation in a number of countries worldwide. Through the work of Juan Díaz, ECC's medical associate in Latin America and the Caribbean, the ECC project participated in all stages of the WHO strategy's implementation in Brazil. ECC staff were also asked to help the Guatemala MOH and WHO to develop and implement a reproductive health needs assessment strategy for Guatemala.

Various factors delayed development of the needs assessment during Year Three of the Population Council Program III. Because the ECC project has been terminated, this project will not be undertaken.

Implementing Organization(s): Population Council
Collaborating Organization(s): Guatemala Ministry of Health
World Health Organization

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.2

Technical Assistance to the Honduras Ministry of Health

Part of project Number/s: 03200

Country/ies: Honduras

Technical Coord.: Juan Díaz

Period: 1995 – July 2001

Objective: To provide technical assistance to the Honduras Ministry of Health (MOH) to prepare national family planning and reproductive health guidelines.

Final Report:

Between 1995 and 2001, the Population Council's Expanding Contraceptive Choice (ECC) project provided technical assistance to the Honduras MOH to prepare family planning and reproductive health guidelines for the country. This assistance took many forms, including conducting contraceptive technology updates, reviewing technical guidance documents, and participating in policy dialogues. During Year Two of the Population Council Program III, ECC staff provided technical assistance to improve the in-country logistics system to make Depo-Provera® available in all clinics; to look for mechanisms to ensure long-term provision of the method; and to continue efforts to improve quality of care and informed choice in reproductive health and family planning programs.

In July 2001, the Council's office in Honduras closed and the ECC project ended its technical assistance to the Honduras MOH.

Implementing Organization(s): Population Council

Collaborating Organization(s): Honduran Family Planning Association (ASHONPLAFA)
Honduras Ministry of Health

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Mission-Funded Initiatives (not ECC-related)

Program Summary

One feature of the Population Council Program III (PCP3) cooperative agreement was its ability to channel USAID mission field support to Population Council field activities that fit within the PCP3's results framework.

In Year One, the Regional Economic Development Services Office for East and Southern Africa (REDSO/ESA) mission contributed to efforts of IPD's Gender, Family, and Development program in Kenya to create fact sheets on various aspects of girls' lives in East and Southern Africa and to carry out case studies of successful livelihood programs for young women in Kenya.

In Cambodia, the USAID mission supported the Council to provide operations research for the mission Office of Public Health's new Population, Health, and Nutrition strategy for 2002–05. Through operations research the project contributed to strengthening the capacity of Cambodia's health system to provide a basic package of essential health services in predominantly rural areas.

The USAID/Egypt Mission in Year One supported Youth Livelihoods in Egypt, a two-year study on young women's labor market opportunities with the goal of identifying policy interventions that would delay marriage and childbearing sufficiently to create conditions in which more "successful" transitions to adulthood could occur. Late in Year Five, the Egypt mission funded research to better understand the slow pace of fertility decline in Egypt and to identify policies that might accelerate the decline.

USAID/India funds originally allocated to the Expanding Contraceptive Choice program in Year One were programmed by Population Council/New Delhi during Year Five for formative research whose findings will contribute to an operations research project on adolescent reproductive health in Uttaranchal.

During Year Three, USAID/Mali requested assistance from IPD's former West and Central Africa regional office for studies to gain a better understanding of the trends in contraceptive use in Mali, and the demand and supply factors responsible for these trends, in order to determine how to reinvigorate the national family planning program and make available high-quality and sustainable family planning services to all who need them, thereby reducing the unmet need for family planning in Mali. Then late in Year Three, USAID/Mali requested a follow-on project to disseminate the information gleaned by the previous study. The mission supported the effort to inform regional and district health service providers of the major study findings, and to enhance use of these findings by sharing and analyzing them, and by compiling program managers' recommendations for future actions.

Fact Sheets on Girls' Lives in East and Southern Africa

Part of project Number/s: 05400

Country/ies: East and Southern Africa Region

Technical Coord.: Annabel Erulkar

Period: August 1999 – December 2000

Objective: To create fact sheets on various indicators pertaining to girls' lives in East and Southern Africa (ESA) to be used as an information resource for program planners and policymakers.

Final Report:

Policymakers and program managers must have a sound understanding of the broad context of young people's lives, such as schooling and livelihood experiences as well as their experience of violence, in order to design appropriate interventions. As a first step toward creating greater awareness and understanding of these issues, the GFD program in Kenya, with support from USAID, developed fact sheets, or briefs, on various aspects of girls' lives in the ESA region. The purpose of the fact sheets is to broaden our understanding of girls and young women in East and Southern Africa.

In all, five fact sheets were produced on the following topics: (1) barriers to girls' education, (2) young women's livelihoods, (3) girls and sports, (4) sexual violence against girls and young women, and (5) tables on the diversity of girls and boys. The last made use of tabular data from Demographic and Health Surveys of six countries in ESA and described educational status, living arrangements, and marital status of boys and girls in the region.

During Year Two, GFD disseminated the fact sheets at the local, regional, and international levels. Dissemination was conducted primarily through existing networks that focus on adolescents; regional meetings; and mailings to Africa-based reproductive health organizations, relevant government institutions, donors, nongovernmental organizations, and youth-serving organizations. To date, over 1,000 copies of the fact sheets have been distributed.

Implementing Organization(s): Population Council

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Case Studies of Adolescent Livelihood Programs in Kenya

Part of project Number/s: **05400**

Country/ies: Kenya

Technical Coord.: Banu Khan

Period: August 1999 – December 2000

Objective: To conduct in-depth case studies of selected programs designed to expand economic options for adolescent girls in Kenya, and provide lessons learned for policymakers and program planners.

Final Report:

There is limited documentation of program experiences in the area of young people's livelihoods. In 1999, drawing from the Population Council's 1997 survey of youth-serving organizations, Council staff selected four local programs in Kenya for documentation. With financial support from USAID, Council staff conducted in-depth case studies of the four programs, which were chosen because they respond in an interesting or innovative way to expanding livelihood options for young women. The documentation is intended to expose readers to a variety of livelihood interventions and encourage practitioner and donor debate about how to strengthen such interventions, given the current economic crisis that plagues Kenya, the fragility of nongovernmental organization (NGO) program funding, and the desperate and multiple needs of poor young women. In order to set these programs in an appropriate context, the case studies are preceded by an introduction that provides background on the socioeconomic environment, an overview of livelihood interventions and the current policy and programmatic responses to youth unemployment, and lessons learned.

The selected programs are (1) IMANI (Incentives from Marianists to Assist the Needy to Become Independent), a Nairobi-based NGO that provides single mothers with vocational skills training, family life education, job placement for graduates, and access to credit for those who wish to start businesses; (2) The Limuru Girls' Centre, a residential vocational training center that provides socially and economically disadvantaged girls in Kenya with skills training in agriculture and garment making; (3) The Sinaga Women and Child Labour Resource Centre, a Nairobi-based program offering literacy, skills, and rights education to girls employed as domestic workers; and (4) The Shanzu Transitional Workshop, a special project of the Kenya Girl Guides Association that offers vocational training to disabled adolescent girls and a residential program that prepares them to lead productive and independent lives within their communities.

The case studies have been finalized. GFD staff have collaborated with organizational program managers to generate additional information and clarify unclear program elements. USAID funds supported Nairobi staff time, communication with collaborating organizations, and travel during the data collection phase. Other donors will support production of the document. The document has been reviewed internally and externally, and content has been finalized. Minor editorial revisions are currently underway.

Implementing Organization(s): Population Council

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Operations Research Support for USAID/Cambodia's HIV/AIDS and Reproductive and Child Health Program

Project Number/s: **05828**
Country/ies: Cambodia
Technical Coord.: Philip Guest
Period: November 2003 – August 2004
Objective: To strengthen, through operations research, the capacity of the health system in Cambodia to provide a basic package of essential health services in predominantly rural areas.

Activity Description:

USAID/Cambodia's Office of Public Health and its nine Cambodia-based partners (cooperating agencies and grantees) have completed three-year and annual workplans for information and service delivery activities under the new Population, Health, and Nutrition (PHN) strategy for 2002-05. These activities began in October 2002 and ran for three years.

The Population Council coordinated and collaborated with University Research Corporation (URC), a USAID partner, to carry out formative research for operations research, which included identifying problems associated with the operation of various components of the national health system in the area of delivery of reproductive tract infection (RTI) services. The Council provided technical assistance to a local partner, the Reproductive Health Association of Cambodia (RHAC), to design and implement the research activities under the project. A final report based on the results of the research was completed and disseminated with the technical assistance of the Population Council.

Final Report:

The current level of knowledge regarding RTIs in Cambodia is limited. There are surveillance data suggesting high levels of sexually transmitted infections (STIs) as well as limited data indicating high levels of non-sexually transmitted RTIs. Although information on the spread of HIV throughout Cambodia has become increasingly available, the dynamics and patterns of the spread of other RTIs are not clearly understood. Part of the objective of this activity was to improve our understanding of both the spread of these RTIs as well as to identify critical program gaps in the provision of services for women and men with sexually transmitted and non-sexually transmitted RTIs in the national health system. This was accomplished by undertaking research which used a facility-based situation analysis methodology that included client interviews.

The study found that the capacity of health care providers in the public and private sectors to provide quality RTI services needs strengthening. Areas of particular importance include the improvement of providers' knowledge of the difference between sexually and non-sexually transmitted RTIs through training; the screening of antenatal care and IUD clients for STIs in maternal and child health (MCH) and family planning sections of health centers through routine supervision; the arrangement of privacy for clients in health centers through the provision of private space, followed up by supervisory checks; and the use of information, education, and communication materials, particularly by health center and MCH section providers, via the development and provision of these materials by the MOH and NGOs.

In addition, the study found that efforts need to be made to improve partner notification. Further

investigation is necessary into the reasons why a substantial proportion of health center providers do not give referral slips to STI clients for their partner(s) because of the belief that the client's STI is not serious enough to warrant it.

Finally, interviews with clients regarding their RTI health-seeking behavior identified several areas where health facilities were not meeting their needs. Clients' perceptions that better quality medicines and a reduction of the long waiting times at NGO clinics are needed should be addressed by further investigation and time and motion studies, respectively.

The results of the study were disseminated in Cambodia at a dissemination workshop organized by the Reproductive Health Association of Cambodia. Participants at the workshop included representatives of Cambodia and international NGOs, and officials from the Ministry of Health.

The research also contributed to developing the applied research capacity of the Reproductive Health Association of Cambodia (RHAC), a leading provider of reproductive and sexual health services in Cambodia. The Population Council worked with RHAC to improve its ability to identify research problems, design programmatic research, conduct high quality data collection, analyze data, and disseminate the results.

The objectives of the activity were accomplished. Research that identified program gaps in service delivery for RTIs in the national health system was conducted and disseminated, and the capacity of local partners was strengthened.

Implementing Organization(s): Reproductive Health Association of Cambodia (RHAC) (I04.06A)
Population Council

Collaborating Organization(s): University Research Corp. (URC)

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Youth Livelihoods in Egypt

Project Number/s: **05405**
Country/ies: Egypt
Technical Coord.: Barbara Ibrahim, Sajeda Amin
Period: December 1999 – March 2002
Objective: To analyze trends and patterns in youth employment and the social context of work for young females in Egypt.

Final Report:

The aims of this project were to learn more about (1) the range of work options and roles available to youth in Egypt; (2) the process of workforce entry and the context in which requisite skills for workforce participation are acquired; (3) the social and psychological impact on young females of their participation in livelihood activities; and (4) the gaps in existing policies and programs addressing youth livelihoods. A research goal was to identify policy and programmatic interventions that could enhance livelihood opportunities for young females.

Quantitative data were gathered through a special module on youth livelihoods attached to the Egypt Labor Market Survey 1998, a nationally representative survey conducted by the Economic Research Forum in collaboration with the government of Egypt. The module was designed by Population Council researchers to broaden the survey's focus by including additional questions on labor-force entry, work history, and educational background and training, as well as questions concerning issues relevant to decisions about marriage and childbearing. A parallel qualitative component consisted of in-depth interviews with young people and key informants.

Data from the 1998 survey were compared with data collected a decade earlier in the government of Egypt's Labor Force Sample Survey 1988. This comparison revealed that young Egyptians were more educated, stayed longer in school, and married later in 1998 than in 1988. Nevertheless, during those ten years, working conditions worsened for Egyptian youth. In 1998, youth unemployment was higher than ever in Egypt, with 4.1 million young people able and willing to work, but out of work. There were fewer permanent jobs, less contractual work, and longer work hours. Wage-work opportunities for youth were scarcer, primarily because of declines in public-sector enterprise and private-sector agriculture. These conditions adversely affected young females more than males. The few opportunities for government and nonagricultural, private-sector work that did emerge during this period benefited young males more than females. Young females were three times more likely to be unemployed than young males and were more than twice as likely to be unemployed than older females. Among unemployed females, more than half had at least eight years of education.

Unmarried females were often willing to accept deteriorating work conditions; however, long hours make work more incompatible with married life. Unmarried female workers expect to quit working for wages when they marry, viewing wage work as a temporary state rather than a lifelong career. This view curtails their incentive to gain livelihood skills, limiting their potential for professional development. Nevertheless, young females benefited from even a temporary stint in the workforce. Female survey respondents reported that working for wages enhanced their self-esteem, increased their communication and negotiation skills, and improved their social and economic standing in their families and communities. Even if young females were able to retain their enhanced self-esteem, their social and economic positions declined after

withdrawing from wage work. This occurred just as they were acquiring the added economic burdens of marriage and childbearing.

The Council has worked with private-sector employers, service-delivery nongovernmental organizations, and policymakers to identify effective ways to remove barriers to workforce entry and to ensure lower rates of dropout from the workforce. These include policies to create new job placement programs; introduction of flexible work hours; steps to promote safer transport to and from work, especially at night; and protection from harassment in the workplace.

Implementing Organization(s): Population Council

Collaborating Organization(s): Economic Research Forum

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Stalled Fertility Transition in Egypt

Project Number/s: **06011**
Country/ies: Egypt
Technical Coord.: John Casterline, Barbara Ibrahim, Rania Roushdy
Period: July 2003 – December 2004
Objective: To better understand the current slow pace of fertility decline in Egypt and to identify policies that might accelerate the decline.

Activity Description:

The research will investigate two interrelated sets of questions. First, fertility has declined slowly in Egypt during the past decade and remains above three births per woman. What are the prospects for acceleration of the decline? What are the obstacles to further decline? What policies might facilitate more rapid decline? Second, economic growth in Egypt is sluggish, at best, and a large proportion of the population remains in poverty. What are the links between household poverty, underemployment, and fertility? What impact does poverty have on reproductive health and fertility goals and decisions? How are household economic circumstances related to the pace of fertility decline?

To address these and related questions, survey data will be collected from a nationally representative sample of the entire country. Two population subgroups will be interviewed: (1) currently-married women of reproductive age; and (2) young, unmarried adults (male and female). In addition to standard fertility survey information, more detailed data will be gathered from these subgroups.

Currently-married women of reproductive age will be asked to provide information on the economic status of the household; their attitudes regarding childbearing, including the perceived costs and benefits of children (and, in particular, the costs and benefits of having three or more children); how childbearing relates to other personal and family goals and its place in respondents' larger value systems; and obstacles to using contraception, including access to and quality of services, social costs, and fear of health side effects.

Young unmarried adults will be asked to provide information on their aspirations for marriage and parenting, including the timing of marriage, first birth, and the spacing of children; and the way these aspirations relate to their educational and employment aspirations, as well as their personal values.

Data will be analyzed with the aim of ascertaining the primary reasons why fertility remains above three births per woman in Egypt and developing policies that might stimulate more rapid fertility decline.

A report will be prepared and submitted to USAID.

Final Report:

The Stalled Fertility Transition (SFT) sample design and selection and questionnaires development and pretesting took place between July 2003 and March 2004. The data collection of the SFT project, the main responsibility of the Cairo Demographic Center (CDC), was conducted between April 2004 and June 2004. The CDC fieldwork team successfully interviewed a nationally representative sample of 3,286 currently-married women, a sample of 917 unmarried women aged 18-29, and a sample of 945 unmarried men aged 18-29. The currently-married women were asked about their reproductive experience, their attitudes on

childbearing and related issues, and household economics. The unmarried respondents were asked about their attitudes towards childbearing and about their attitudes and expectations regarding marriage.

The analysis of the SFT data and the preparation of the brief report took place between July 2004 and December 2004. The data show that a transition from Egypt's current fertility rate of 3.2 births per woman to the replacement level (the fertility rate consistent with a population growth rate of zero, which is regarded as 2.1 births per woman) will require reductions in both wanted and unwanted fertility; neither a reduction in wanted fertility nor in unwanted fertility alone will be sufficient. Also, the data reveal that widespread acceptance of a two-child norm is lacking at present among both the currently-married women of all ages and the never-married youth. This lack of widespread acceptance of a two-child norm is the most notable obstacle to the achievement of replacement-level fertility.

Another obstacle to the achievement of replacement-level fertility revealed by this study is that, despite the fact that few women perceive much gain from having a large number of children and most acknowledge the advantages of having just two children, a substantial fraction still desires three or more children. It seems that "intellectual assent" to the benefits of a small family is not, in itself, sufficient to lower fertility. Additionally, most Egyptians wish to have both a son and a daughter. This sex preference on balance works against replacement-level fertility, because one-half of the couples with two children will lack either a son or a daughter.

The brief report on the key study findings was prepared and sent to USAID in December 2004 for revisions and comments. In addition, five scientific papers using the SFT data were prepared and presented at international conferences, one paper was presented at the 11th Economic Research Forum Annual Seminar in December 2004 in Beirut, two at the 2005 Population Association of America (PAA) Annual Meeting in March in Philadelphia, and two at the XXV International Union for the Scientific Study of Population (IUSSP) International Population Conference in July 2005 in Tours, France. Papers based on those presented at the above-mentioned conferences will be prepared and submitted to scientific journals for publication. With these activities the study team has accomplished all the objectives of the SFT project planned under the PCP3.

After the successful completion of the SFT PCP3 activities in December 2004, the study team was able to obtain supplementary funds from the USAID/Egypt mission through the Population Council's FRONTIERS program for the period January 2005 through September 2005. These additional funds allowed the study team, in collaboration with FRONTIERS staff, to complete the scientifically-sound and policy-relevant analysis of the SFT data; a long report and three in-depth analysis papers of the SFT data; and two seminars in December 2004 and July 2005 which allowed the project findings to be disseminated to key audiences in Egypt. All the SFT project publications are expected to be available by the end of 2005.

Implementing Organization(s): Cairo Demographic Center (CDC) (I04.12A)
Population Council

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Addressing Adolescent Reproductive Health Needs: An In-Depth Study of the Gate Keepers in Uttaranchal

Project Number/s: **44504**
Country/ies: India
Technical Coord.: M.E. Khan
Period: April 2004 – August 2005
Objective: To assess the opinions of different gatekeepers in Uttaranchal, India about introducing reproductive health education for young people.

Activity Description:

In order to assess the opinions of different gatekeepers in Uttaranchal, India about introducing reproductive health education for young people, the study will collect data from parents, teachers, formal and informal community leaders, religious leaders, and development officials. The findings of the study will contribute to initiation of an operations research study addressing the reproductive health needs of young men.

Both qualitative and quantitative methods are being used to collect relevant information. The primary methods include in-depth interviews, focus group discussions, and self-administered questionnaires for selected school students. Data will be collected at different levels. At district headquarters, officials in general administration, education, health, Panchayat (village council), and Integrated Child Development Services (ICDS), will be interviewed. Similarly, corresponding officials will be interviewed at the administrative block level. At the village level, formal and informal community leaders (Panchayat members, school teachers, religious leaders, and youth leaders of various clubs and associations), parents, and a sample of male and female high school students will be interviewed.

The interviews will seek to find out: (1) views and perceptions on the need for such education for young people; (2) views and perceptions on how such a program could best be implemented: Should it be included in school curricula? What other methods could be used to reach both in- and out-of-school adolescents?; (3) What role do the parents and other gatekeepers feel they could play in such an effort? Are they willing to participate in the implementation of the program?; (4) What are the topics they feel should be given special attention?; (5) Would they like to receive some orientation on those topics so that they could help guide their children or community workers to support the initiative?; (6) What local and community resources could be mobilized for introducing and sustaining such an initiative?

Final Report:

The study was carried out in Udham Singh Nagar, a district in the state of Uttaranchal. Data was collected from four villages, two each from two administrative blocks. Thirty-two in-depth interviews and four focus group discussions were conducted with gatekeepers, including parents, teachers, formal and informal community leaders, religious leaders, and development officials. To complement observations made by the gatekeepers, information from 234 male and 189 female 11th and 12th grade students was collected using self-administered questionnaires in the classroom setting.

Analysis of parents' and other gatekeepers' views on the sexual and reproductive health (SRH) needs of young people indicates worries about the rapid changes in the aspirations, expectations, and behaviors of young people. While some of the changes are encouraging, as perceived by the parents and gatekeepers, many others are considered harmful for both the young generation and the community as a whole. Most of

the parents and gatekeepers were seriously concerned about increasing drinking habits, use of drugs, and changing values of sexuality among young men. The parents and gatekeepers also expressed concern for the erosion of respect for elders and the increase in violence and crime. The parents and gatekeepers felt that many of these changes are the consequence of wider societal changes, rising aspirations, the explosion of electronic media, easy access to pornographic movies (even in rural areas), and the globalization of a new youth culture in which extramarital sex, alcohol consumption, and violence can be expressions of masculinity and a symbol of being a member of an affluent class. Parents felt that with erosion of respect for elders, parents alone may not be very effective in addressing their children's SRH information needs. Hence, all the parents and gatekeepers supported the idea of introducing a community-level intervention addressing these issues, and, in particular, supported addressing risky behaviors related to sex and violence.

The findings from the school surveys and the qualitative data collected from young men from the community complemented the gatekeepers' observations. The young men were of the view that, in general, parents are not in a position to guide them because of their lack of knowledge of changing opportunities and challenges and the technological advancement and aspiration of the young generation. They did not agree that they do not respect their parents. The young men said that their parents do not understand that young persons also need to be treated with dignity and that their views also should be appreciated.

Findings show that, in general, both male and female students were opposed to using any violent means to control a woman, except if a woman is suspected of having an affair. Restrictions on girls for higher education or for going outside the home to work were considered unjustified and were perceived as violence against girls by both the male and female students. The expression of approval for the use of violence to control women was more common among those students who had witnessed such violence in their family, and by those who had scored high on the masculinity scale.

To a great extent, students' responses supported a liberal sex attitude: more than half of the male students approved of pre-marital sexual intercourse between two people of the opposite sex in love with each other; 21 percent of the male students had experienced sexual intercourse; and 40 percent of the male students had at least one close friend who was sexually active. The median age for first sexual intercourse was 15 years.

The findings demonstrated that although adolescents have some knowledge on HIV/AIDS and how to protect oneself from infection, their knowledge related to reproduction, STDs, and contraception has remained low and superficial. Young people's information needs regarding SRH issues are not being fully met, and, in fact, the young people asked for the provision of accurate SRH information. They reported that peers, doctors, films and magazines, and teachers were their preferred sources of SRH information.

The study identified some of the key institutions which could play significant role in an SRH initiative. These included rural health facilities like primary health centres (PHCs), block development offices (Youth Welfare and Village development), Panchayat, village development committees, and informal youth groups like Yuvak Mangal Dal and Mahila Mangal Dal. Based on the findings of this project, a conceptual framework has been developed for an OR study to address young men's SRH needs.

Implementing Organization(s): Population Council

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Factors Affecting Contraceptive Use in Mali

Part of project Number/s: **04607**
Country/ies: Mali
Technical Coord.: Ayo Ajayi
Period: July 2001 – December 2001
Objective: To identify factors responsible for low levels of contraceptive use in Mali.

Final Report:

In the 1990s, Mali's total fertility rate was the second highest in Africa (6.7 in 1996), after Niger (7.2 in 1998). Use of modern contraceptive methods among married Malian women of reproductive age rose from an average of 1.3 percent in 1987 to 4.5 percent in 1996 to 5.7 percent in 2001, according to the Demographic and Health Surveys (DHS). These average rates obscured large urban/rural differentials in contraceptive use: between 1987 and 1996, contraceptive prevalence jumped from 5 to 12 percent in urban areas, but increased only 0.1–2 percent in rural areas of Mali. In 2001, two-thirds of the country's modern contraceptive users lived in urban areas, close to half of them in Bamako.

This study set out to identify factors responsible for low contraceptive use in Mali, using its 1987, 1996, and 2001 DHS data sets. Its findings were as follows.

Between 1996 and 2001, rural/urban differentials in infant mortality began to change the pattern of contraceptive prevalence. During this period, contraceptive uptake was much slower in urban areas, where infant mortality was on the rise, than in rural areas, where infant mortality declined. Females with some formal education comprised half of Mali's modern contraceptive users (only one-fifth of Malian females of reproductive age were educated); yet contraceptive prevalence declined among educated urban females between 1996 and 2001.

In 2001, one-third of Malian women had a need for contraception; yet one-third of those in need of contraception were not using it, DHS data showed. Women's and men's disapproval of contraceptive methods, lack of family planning information, and couples' desire for more children have been the main impediments to modern contraceptive use in Mali.

The trends outlined above indicate a need for more programmatic attention to quality of care in family planning and to child survival, particularly in urban areas of Mali. Community-based distribution programs must be strengthened to maintain the decline in infant mortality and the rise in contraceptive prevalence in rural Mali. An information, education, and communication strategy to raise family planning awareness should focus on rural areas and should provide not only information about contraception but also education on the merits of smaller families.

Implementing Organization(s): African Population and Health Research Center (CI01.46A)
Population Council

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Assessment of the Availability and Functioning of Family Planning Services in Mali

Part of project Number/s: **04607**
Country/ies: Mali
Technical Coord.: Seydou Doumbia
Period: July 2001 – December 2001
Objective: To assess the availability and functioning of family planning services in Mali.

Final Report:

For decades, governmental institutions, national and international nongovernmental organizations, other international institutions, and bilateral cooperating agencies have supported family planning initiatives in Mali. Despite these efforts, data from recent studies show that contraceptive prevalence remains low in this country. Seeking to determine the factors contributing to this low prevalence, USAID/Mali commissioned a series of three studies of service delivery in stationary health centers in Mali. This Population Council assessment was part of these studies.

The Council study used a modified situation analysis (SA) methodology to assess the readiness of staff and facilities to offer family planning services. Data were derived from in-depth interviews with policy and programmatic decisionmakers, inventories of service-delivery points (SDPs), and interviews with service providers. (Because of time limitations and the low contraceptive prevalence rate, it was not practical to assess service quality.) The study looked at a sample of SDPs in the district of Bamako and in the regions of Kayes, Koulikoro, Mopti, Ségou, and Sikasso. Efforts were made to include all health centers that have served as backup clinics for the community-based distribution (CBD) program in Mali.

Research activities consisted of (1) developing and adapting standard SA methodology and questionnaires for the study; (2) visiting SDPs to collect data to assess their functional capacity and the technical capabilities of service providers, including their information, education, and communication skills; (3) analyzing data; (4) organizing a national workshop to disseminate study results and to define priority areas for USAID/Mali's ten-year (2003–12) strategic plan; and (5) preparing a report of findings that includes specific recommendations for this plan.

Assessment activities were carried out between July and December 2001 in four phases. (The first three phases were executed in tandem with the three phases of the activity "Assessment of the Functioning and Effectiveness of the Community-Based Distribution Programs in Mali" [see page 73].)

Phase 1: Preparatory activities (July–August 2001). The main activities carried out during this period were recruitment and orientation of the research team, preliminary field visits, development of data collection instruments, and training of interviewers. A research team composed of a project coordinator and two research assistants was hired to monitor study activities. Staff from the Council and from the Mali Ministry of Health's Division of Reproductive Health conducted a joint visit to the five regions in the study to brief officials about the study's objectives and methodology. This visit exposed researchers to the realities of the field, allowing them to adjust their research strategy accordingly. Development of data collection instruments consisted of adapting/revising SA questionnaires and producing a guide to interviewing decisionmakers and health officials.

Three sources were used for data collection: the SDP inventory guide, the SDP staff interview

questionnaire, and the guide to interviewing decisionmakers and health officials. Fifty data-collection agents were selected after a competitive six-day training.

Phase 2: Data collection (September 2001). During this month, ten teams of four interviewers visited the five regions and the district of Bamako to collect data. Three teams went to Koulikoro, three to Sikasso, one to Kayes, one to Mopti, one to Ségou, and one to Bamako. Each team was composed of a doctor, a midwife, and two survey specialists. To ensure research quality, the teams closely supervised data collection.

Phase 3: Data entry and analysis (October–November 2001). Activities during this phase included quality control checks of completed questionnaires (for data consistency and completeness), computer entry of data, data tabulation, and data analysis. Working in the Council's Bamako office, nine experienced data-entry clerks computerized data using EPI DATA software in the EPI INFO environment. Data were later imported into STATA 7.0 for analysis. Following frequency tabulation of key variables, the research team produced a preliminary data analysis that was later enriched by the recommendations of a three-day workshop on interpreting preliminary data from the study, held in Selingué. Data were jointly analyzed with CBD assessment study data.

Phase 4: Production of report (December 2001). The preliminary report of the study was produced in French; this report was then revised and translated into English. Final French and English versions of the report will be produced and distributed widely, pending Council approval.

Collaborating Organization(s): Mali Ministry of Health Division of Reproductive Health

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Assessment of the Functioning and Effectiveness of the Community-Based Distribution Programs in Mali

Part of project Number/s: **04607**
Country/ies: Mali
Technical Coord.: Seydou Doumbia
Period: July 2001 – December 2001
Objective: To provide information to guide the design, management, and testing of alternative models of community-based family planning programs in line with Malian norms and procedures.

Final Report:

This study consisted of an assessment of all community-based distribution (CBD) programs in Mali, with a focus on USAID-funded programs. Information about the programs was collected from organizations' headquarters in Bamako, as well as from service-delivery sites. In the field, information was obtained from CBD agents and their supervisors, referral clinics, and community representatives in the regions of Kayes, Koulikoro, Mopti, Ségou, and Sikasso, where CBD programs were being implemented. Data were collected on the locations of CBD programs, number and type of CBD agents, services offered by agents, ways in which agents operate, supervision and motivation of agents, service outputs, and any implementation problems that organizations faced. This information was collected from a sample of CBD agents, through individual interviews and focus group discussions; from interviews with staff of programs and referral clinics; and through review and analysis of service statistics.

The CBD assessment activities were carried out between July and December 2001 in three phases: preparatory activities, data collection, and data entry/analysis. (These phases were executed in tandem with the first three phases of the activity "Assessment of the Availability and Functioning of Family Planning Services in Mali".)

Phase 1: Preparatory activities (July–August 2001). The main activities carried out during this phase were: recruitment and orientation of the research team, preliminary field visits, development of data collection instruments, and training of interviewers. A research team composed of a project coordinator and two research assistants was hired to monitor daily research activities. Staff from the Council and from the Mali Ministry of Health's Division of Reproductive Health conducted a joint visit to the five regions in the study to brief officials about the study's objectives and methodology. This visit exposed researchers to the realities of the field, allowing them to adjust their research strategy accordingly. Development of data collection instruments consisted of adapting/revising situation analysis questionnaires and producing a guide to interviewing decisionmakers and health officials. Six different sources were used for data collection. Fifty data collection agents were selected after a competitive six-day training.

Phase 2: Data collection (September 2001). During this month, ten teams of four interviewers each visited the five regions and the district of Bamako to collect data. Three teams went to Koulikoro, three to Sikasso, one to Bamako, one to Kayes, one to Mopti, and one to Ségou. To ensure research quality, teams closely supervised data collection.

Phase 3: Data entry and analysis (October–November 2001). Activities implemented during this phase included quality control checks of completed questionnaires (for data consistency and completeness),

computer entry of data, and data analysis. Working in the Council's Bamako office, nine experienced data-entry clerks computerized data using EPI DATA software in the EPI INFO environment. Data were later imported into STATA 7.0 for analysis. Following frequency tabulation of key variables, the research team produced a preliminary data analysis that was later enriched by the recommendations of a three-day workshop on interpreting preliminary data from the study, held in Selingué.

In December 2002, the preliminary report of the study was produced in French; this report was then revised and translated in English. Final French and English versions of the report will be produced and distributed widely, pending Council approval.

Implementing Organization(s): Population Council

Collaborating Organization(s): Mali Ministry of Health Division of Reproductive Health

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Regional Dissemination of the Family Planning Program Assessment Study Findings in Mali

Project Number/s: **04608**
Country/ies: Mali
Technical Coord.: Seydou Doumbia
Period: June 2002 – December 2002
Objective: To inform regional and district health service providers of the major findings of the Mali Family Planning Program Assessment, and to enhance use of the findings through analysis and dissemination and through compiling program managers' recommendations for future action.

Activity Description:

This activity consisted of analyzing Mali Family Planning Program Assessment data by region and presenting the results to the appropriate audiences in each region, including decisionmakers from the Mali Ministry of Health (MOH), service providers, nongovernmental organizations, and donors. Specific activities included holding a planning workshop with participants from each of the regions; reprinting and distributing more widely the Mali Family Planning Program Assessment study report; preparing and distributing a summary of major findings of the assessment; analyzing the data from each region; preparing regional reports and presentations; conducting regional workshops and briefings; distributing regional reports; and monitoring and reporting on the dissemination process and its impact.

Final Report:

The Population Council, in collaboration with the Mali MOH, organized six regional dissemination workshops over a six-month period (July–December 2002) to disseminate the results of the Mali Family Planning Program Assessment in the following regions: Bamako, Kayes, Koulikoro, Mopti, Ségou, and Sikasso. In preparation for the two-day workshops, one health professional from each region was chosen to attend a two-day planning meeting to determine the objectives of regional dissemination efforts, develop a format for presenting study results at the regional level, identify priority reproductive health issues for each region, and plan the workshops.

The first day of the workshops consisted of a presentation of the findings of the family planning program assessment followed by presentation of regional results. Presentations were made by a national MOH team and the regional medical chief and family planning coordinator. The second day consisted of small group discussions regarding the findings and recommendations for further improvements, and a plenary session to discuss the various recommendations. The workshops were designed for staff of MOH health services, service providers, MOH decisionmakers, donors, and representatives from NGOs working in the health sector in Mali. Attendees included medical doctors (69), nurses (52), managers (48), midwives (48), community representatives (74), staff from NGOs (30), MOH decisionmakers (16), journalists (30), and representatives from USAID Mali (3), UNFPA (2), UNICEF (1), and WHO (2). The workshops were covered by national television and local radio stations, and members of the media took part in the working groups, where they asked to be more involved in information dissemination and sensitization efforts regarding family planning services.

The main recommendations that emerged from the workshops included improving: the quality of family planning services at service delivery points; the quality of care of the community-based distribution program; and dialogue among policymakers, MOH decisionmakers, and community leaders regarding

family planning programs. To monitor dissemination of results, a dissemination activity coordinator assisted by MOH staff collected information on the number of participants in the regional workshops and ensured that all reports, presentations, and visual aids were provided to their respective audiences. About 600 copies of the final report have been printed and distributed throughout Mali to MOH administrators, health program managers, service providers, national and regional policymakers, other government ministries concerned with reproductive health, NGOs, women's organizations, donor agencies, and USAID-funded cooperating agencies. In addition, the final report for each region, including recommendations from the regional workshops, has been produced. About 150 copies have been printed and distributed in each region.

Note: The activity reported here was also carried out, during January through May 2003, under a separate purchase order contract between USAID/Mali and the Population Council.

Implementing Organization(s): Population Council

Collaborating Organization(s): Mali Ministry of Health

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Core-Funded Initiatives

Program Summary

Core-funded initiatives were Population Council activities that were not part of any other program supported by the Population Council Program III (PCP3) but had results and objectives that matched those of the PCP3 results framework and were found worthy of core support. Support came from either general USAID Office of Population core funds or from the USAID Population Office special initiative (later renamed "global leadership priority") committee on female genital cutting.

"Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing" (Impact Studies) sought to document the feasibility of improving quality of care in family planning programs and to assess the impact of improved quality of care on women's ability to reduce unplanned and unwanted childbearing in a healthful manner. The Population Council initiated the program in 1995 in response to the call for client-centered reproductive health services issued at the 1994 International Conference on Population and Development. Field studies in four countries—Pakistan, the Philippines, Senegal, and Zambia—were launched between 1997 and 1999. Interventions tested in these countries aimed to improve client–provider interactions, increase contraceptive choice, and facilitate other improvements in quality of care. USAID provided partial support for this program with USAID FY01 core funds, which assisted the program during Years Three and Four. (Some work in Zambia was also funded under the ECC program. See activity "Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two".)

Studies in Family Planning, a peer-reviewed international quarterly published by the Population Council since 1963, is the foremost journal in the field to provide an evidence-based approach to reproductive health programs and policies in developing countries. USAID provided funding in Year Five to help defray a loss of support from UNFPA, whose severe funding shortfalls forced it to cut back drastically on its support to NGOs. USAID's funding helped to sustain *Studies* during 2003 at the level of excellence that the field has come to rely on.

The INTACT Network (the International Network to Analyze, Communicate and Transform the Campaign Against FGM/FGC/FC) addresses the limitations on research on female genital cutting through a network of researchers and research-minded activists. It contributes to the quality and productivity of research and to strengthening links among researchers and between researchers and those who can use the information they generate. During Year Five the USAID FGC Special Initiative Committee redirected funds to the INTACT Network which had been allocated during Year Four to a project that had met with delays.

Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing

Project Number/s: **03507**
Country/ies: Philippines, Senegal, Zambia
Technical Coord.: Anrudh Jain, Saumya RamaRao
Period: January 2002 – June 2003
Objective: To demonstrate the feasibility of improving quality of care and to assess the effects of improved quality of care on women's ability to avoid unintended childbearing.

Activity Description:

Despite recognition of the need to improve the quality of care in family planning programs, progress has been hindered by limited documentation of the effects of efforts to improve quality of care. Results of this Population Council project will facilitate quality-of-care improvements in large, public-sector family planning programs.

Researchers hypothesized that clinics that were part of the experimental group, where interventions were tested, would offer clients significantly better quality of care than would control clinics. Three interventions were tested in the field: (1) improving the content of information exchange between providers and clients in the Philippines; (2) adding a contraceptive method to the existing method mix in Zambia (see "Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two"); and (3) improving overall quality of care in clinics in Senegal. Information on quality of care was collected in three rounds, using situation analysis methodology. Information on client knowledge and reproductive behavior was collected in three rounds of interviews with a panel of family planning clients and women who live in the vicinity of clinics

Final Report:

Funding from the Population Council Program III (which ended in June 2003) was crucial for conducting secondary analysis of data already collected under the Council's Impact project. In the past, the project received funding from the USAID-funded Africa and Asia OR projects, The Rockefeller Foundation, and the Population Council. Further analysis of the data will take place with funding from sources yet to be determined.

Initially, project activities included cleaning and conducting quality checks on the data from each country. Efforts were then made to link data sets; for example, interviews conducted over time with the same individual were linked to exploit the longitudinal nature of the data; information collected at facilities from providers and clients was also linked. Subsequent activities included testing the research hypotheses and documenting results. The prepared data were analyzed and the findings documented in scientific papers, several of which were published in peer-reviewed publications. "A client-centered approach to family planning: The Davao Project" presented results of the study in the Philippines and was published in the journal Studies in Family Planning in December 2001. "Learning how to learn about clients: Family planning field workers in the Philippines" was included in the book Responding to Cairo: Case Studies of Changing Practice in Reproductive Health and Family Planning, published by the Population Council in 2002. "Dual needs: Contraceptive and sexually transmitted infection protection in Lusaka, Zambia" was published in the journal International Family Planning Perspectives in June 2002.

Data from the Philippines and Senegal were analyzed to test the effect of improving the quality of care on contraceptive continuation. Results from these analyses will be published in 2003. Findings from the Philippines are documented in "The link between quality of care and contraceptive use," recently published in International Family Planning Perspectives (June 2003). "Improving quality and contraceptive use in Senegal" is forthcoming in African Journal of Reproductive Health. Finally, a literature review documenting the various interventions to improve quality of care and the body of research on this topic was prepared and submitted to the journal Studies in Family Planning for possible publication.

In summary, the results from these field studies indicate that the interventions tested in all countries were able to improve the service environment; clients who visited facilities in the experimental group where service improvements took place received better care than those who visited similar facilities in the control group; contraceptive continuation among clients exposed to the intervention was slightly higher, albeit not statistically significant; and the quality of care that clients received had a significant and positive effect on contraceptive continuation.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Studies in Family Planning

Project Number/s: **02800**
Country/ies: United States
Technical Coord.: Julie Reich
Period: July 2003 – December 2003
Objective: To provide funds for the publication of two issues of Studies in Family Planning.

Activity Description:

Studies in Family Planning, a peer-reviewed international quarterly published by the Population Council since 1963, is the foremost journal in the field to provide an evidence-based approach to reproductive health programs and policies in developing countries. In addition to country- and program-specific reports, Studies publishes review articles and concept pieces that are on the cutting edge of research. Each issue also contains a data section with findings for individual countries from the Demographic and Health Surveys, signed book reviews, and, periodically, a scholarly commentary about a topical issue.

Studies covers all aspects of family planning and reproductive health, including a broad range of emerging topics such as adolescent reproductive and social behavior, maternal mortality and morbidity, and the impact of HIV/AIDS on sexual behavior. *Studies*' roster of authors includes leading authorities in such fields as demography, sociology, anthropology, and health sciences. The journal's readership consists of policymakers, research scholars, program managers, and health-care professionals in developed and developing countries.

As of the end of volume 33, *Studies* has a circulation of 5,500, 68 percent of which is distributed free-of-charge to institutions and individuals in developing countries. The journal is also available electronically in a word-searchable format to subscribers through the Population Council's Web site. Each issue is posted online simultaneously with publication of the print edition. Subscribers have access to complete issues from 1998 on.

Final Report:

In 2003, two issues of *Studies in Family Planning*, vol. 34 no. 3 (September) and vol. 34 no. 4 (December), were published with funding from USAID. The monies helped to fund editing, production, and free distribution of copies to institutions and individuals in the developing world.

These issues can be accessed online at www.blackwellpublishing.com/sfp.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Confronting Female Genital Cutting: Assessing a Community Intervention in Egypt

Project Number/s: **05460**
Country/ies: Egypt
Technical Coord.: Barbara Mensch
Period: July 2002 – December 2002
Objective: To measure the efficacy of a community-based intervention designed to reduce female genital cutting (FGC) in Upper Egypt using controlled field conditions and a pre-test/post-test quasi-experimental design.

Activity Description:

Until recently, the practice of female genital cutting, or circumcision, has been a near-universal practice in Egypt. Demographic and Health Survey studies consistently report prevalence levels above 95 percent for ever-married women ages 15–45. Despite government and nongovernmental organization (NGO) efforts at eradication, the practice remains an entrenched aspect of life in Egypt. As public debate around the practice has increased, some parents appear to be responding by having the procedure performed by licensed physicians rather than traditional practitioners, or, among the better educated, by abandoning the practice altogether. A 1997 national survey of girls ages 10–19 estimated that the probability of a girl eventually becoming circumcised had declined, but only to 85 percent.

Addressing this traditional practice through policy and program efforts is extremely difficult. Medical practitioners are not trained to provide counseling on FGC and may in fact profit from performing the operation. Older family members and community elders often put pressure on parents who are undecided about whether or not they should have their daughters circumcised. In addition, decisions concerning FGC are typically made before a girl reaches puberty, long before she is ready for marriage. Therefore, families must be persuaded to abandon the long-standing practice without any immediate assurances that their decision to not circumcise will not affect their daughters' marriage prospects. A further complication is that some previous program efforts that have focused on the health dangers of FGC have not resulted in a reduction in the practice, but rather a shift in who performs it, from traditional practitioners to physicians and nurses.

There is a lively debate in the Egyptian NGO community over best practices with regard to FGC eradication efforts. While a number of interventions are underway, there are few hard data about effective strategies. The Population Council worked with the National Council for Childhood and Motherhood, a governmental agency, as well as the Egyptian NGO Taskforce to Eliminate Female Genital Mutilation. These two organizations are collaborating with the UNDP on an intervention to reduce FGC in 60 predominantly rural communities in Upper Egypt. Although details of the intervention have yet to be worked out, the approach to behavior change that is likely to be taken and that is receiving considerable attention in Egypt is known as "positive deviance." In this model, uncircumcised adult women who are respected figures in their communities are identified and trained to conduct discussions with neighbors that address the health, emotional, and social dimensions of FGC. In one variant of this approach, families are then asked to make a public declaration that they will not circumcise their daughters. The Council, with USAID funding, was asked to take the lead in the design of the process and impact evaluation of this project. Council researchers proposed to measure the efficacy of the positive deviance approach, using controlled field conditions and a pre-test/post-test quasi-experimental design.

Final Report:

In July 2002 technical monitor Barbara Mensch and Council staff member Wesley Clark traveled to Cairo to work with Barbara Ibrahim, the Council's regional director in West Asia and North Africa. During this visit they met with Dina el Naggar of the United Nations Development Programme (UNDP) to discuss details of the intervention. They also met with Fatma El-Zanaty, who has been responsible for conducting Demographic and Health Surveys in Egypt, and discussed her potential involvement in the baseline and endline surveys. Baseline data were to be collected from mothers in the experimental and control sites using a survey instrument that included questions about background characteristics, intent to circumcise daughters, circumcision status of mothers and daughters, circumstances surrounding the procedure for daughters, and current knowledge and attitudes toward FGC. Draft questionnaires were prepared and reviewed during the summer of 2002. In addition, Council staff based in Cairo conducted preliminary qualitative work in Beni Suef, one of the governorates in which the intervention was to take place. Subsequently the project faced considerable delays. Furthermore, the NCCM decided that research efforts should be scaled back in scope, excluding any household-based data collection, and that research should be conducted by Egyptian NGOs. In light of these developments, the Council offered its draft questionnaires to the project staff, and activities ceased at the end of 2002.

$70,129 of the funds originally allocated to this activity were reallocated by USAID to "The INTACT Network for FGM/C Research and Change."

Implementing Organization(s): Population Council

Collaborating Organization(s): Egyptian NGO Taskforce to Eliminate Female Genital Mutilation
National Council for Childhood and Motherhood (NCCM)

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 3.1

The INTACT Network for FGM/C Research and Change

Project Number/s:	**06500**
Country/ies:	Egypt
Technical Coord.:	Barbara Ibrahim, Nahla Abdel-Tawab, Abeer Salem, Mona Bur, Gihan Hosny, Dina Hatem
Period:	August 2003 – August 2005
Objective:	To promote and disseminate evidence-based research and to actively engage donors, local actors, government, and civil society organizations in a dialogue around applying collective learning to accelerate positive social change.

Activity Description:

Through the initiative of the Population Council, a conference on female genital cutting (FGC) took place at the Bellagio Study and Conference Center from April 29 to May 3, 2002 which was funded under the activity "Conference to Advance Research on Female Genital Cutting" (project #04701). Conference participants reviewed the status of FGC research, identified research gaps, and proposed research priorities. An important objective of the conference was to develop a network of researchers, program managers, and other relevant individuals and institutions to enhance communication and the use of FGC research results.

In the weeks following the conference, an Internet-based discussion took place between the participants that further advanced the objectives, mechanisms, and priorities of the proposed network. A technical committee and task groups were formed to launch a website (www.INTACT-Network.net), publish a monograph of the Bellagio papers, and develop funding proposals to support future activities of the network, including training workshops on the transmission of collective learning about behavior change in communities to NGO leaders, internships for young scholars, and technical seminars and conferences. A founding document was circulated during the summer of 2002 to the group for comment and has been adopted by the network to guide its work.

Barbara Ibrahim of the Council's West Asia and North Africa region offered the facilities of her Cairo office to coordinate the work of the technical committee in launching the network. The network will be strengthened to the extent that it is able to expand its dynamic membership to include other key institutions and individuals with strengths in FGC research.

Final Report:

INTACT has strived towards meeting its objectives, and major accomplishments have included the global expansion of network membership, development of website features, inauguration of a research seminar series, and contributions towards capacity-building of NGOs working towards the abandonment of FGC.

1. *Global Expansion of Membership:* In August 2003, INTACT had a membership of 20 people; as of September 2005, membership includes 284 individuals comprising a strong pool of experts in the field of FGC and a wide array of activists representing international organizations, donor groups, academic institutions, grass-roots level NGOs and independent interests. These members form a global community of advocates for the abandonment of FGC. The group communicates via INTACT's website, liased by the network coordinator and regularly updated with info-bulletins outlining recent research publications, policy-relevant news items, web links to other initiatives on FGC abandonment, and research queries.

2. *Development of Website Features:* Launched in June 2003, INTACT's website offers free-access pages that perform multiple functions, including publication of research findings, newly-published papers and

working papers, and links to FGC bibliographies, paper abstracts, meeting summaries, and presentations. The website also announces technical workshops, funding opportunities for research, and other news of relevance for members. A directory of FGC experts and researchers including their research interests and contact information is available online. There is a research news board and message forum where participants can post queries and exchange information in real-time. The website also provides links to other FGC interventions and initiatives that share in our mission. In the 2004 USAID-IAWG assessment, *Information on Female Genital Cutting: What is Out There? What is Needed?*, INTACT Network's website received high marks as being one of the top three FGC websites.

3. *Inauguration of INTACT Research Seminar Series:* INTACT seminars will bring together small groups of experts to focus on specific topics of importance in an effort to identify FGC research gaps. The first seminar, *Advancing Knowledge of Psycho-Sexual Effects of Female Genital Cutting: Assessing the Evidence*, was held October 10–12, 2004 in Alexandria. This seminar included presentations on 12 research papers and in-depth thematic discussions on ongoing research on psycho-sexual effects of FGC, socio-cultural aspects of sexuality, interventions addressing consequences of FGC, Egyptian research and intervention efforts, ethical and methodological issues, and linking research to action. Attendance was diverse and stimulating: attendees included 23 researchers, activists, and program advisors, with a wide range of expertise on FGC, social and behavior change, gender, and reproductive health. The seminar report has been published and disseminated to INTACT members, seminar participants, FRONTIERS and USAID FGC point persons and to program managers globally who have expressed interest.

4. *Collaboration with Four Agencies on the USAID-FGC IAWG information assessment*, Female Genital Cutting: What is Out There? What is Needed?, *July 2004:* Using interviews and questionnaires, INTACT collected information from groups, researchers, and activists working to eradicate FGC in Egypt to identify the gaps in the information available on FGC. INTACT synthesized the findings from Burkina Faso, Egypt, Guinea, and Senegal in collaboration with the Population Council in Senegal.

5. *Provision of Capacity Building for NGO Leaders Working to Eliminate FGC:* To contribute to the capacity building of NGOs working towards the abandonment of FGC, INTACT sponsored RAINBO's *Pilot Regional Training Workshop on Design, Monitoring and Evaluation of anti-FGC Projects Using the Women's Empowerment Community Consensus Framework (WECC)*. The workshop was held in Cairo on March 7-11, 2004 under the auspices of the Egyptian National Council of Childhood and Motherhood.

6. *Presentation at regional training workshop, Abandoning FGC:* Communicating Information and Better Practices to Policy Makers, *August 25 – September 5, 2003, Addis Ababa:* INTACT presented on "Strengthening Links Between Media Professionals and FGC Researchers in Egypt" to representatives from Egypt, Ethiopia, Gambia, Guinea, Kenya, Nigeria, and Sudan as part of the regional policy communication workshop, supported by the Population Reference Bureau, to develop strategic planning and communication skills for improving FGC abandonment policies and programs.

Implementing Organization(s): Population Council

Collaborating Organization(s): Population Council, Frontiers in Reproductive Health

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 2.1

Experimental Family Planning Studies in Rural Africa

Program Summary

The Population Council's Experimental Family Planning Studies in Rural Africa program had two major components: the Community Health and Family Planning project (CHFP) and the Community-based Health Planning and Services initiative (CHPS) in Ghana. The CHFP tested innovative strategies for health and family planning service delivery in rural areas of the country; CHPS is a nationwide service-delivery strategy modeled on the CHFP.

The Community Health and Family Planning Project

The impact of family planning programs on fertility in rural Africa has been debated in the policy literature for three decades; a more recent debate surrounds the question of whether expanding access to health services will improve child survival. To help resolve these issues, the Navrongo Health Research Centre (NHRC) in northern Ghana, under a subagreement with the Council, launched the CHFP—a field experiment testing the relative demographic impact of four approaches to providing primary health care and family planning services in the rural, traditional district surrounding the town of Navrongo. The CHFP began as a pilot project in 1994; it was scaled up to a district-wide trial in 1996.

Results of the experiment show that posting nurses to community locations reduced childhood mortality rates by over half in three years, and accelerated attainment of the childhood survival Millennium Development Goal (MDG) in the study areas to six years. Adding community mobilization strategies and volunteer outreach to this approach led to a 15 percent reduction in fertility, representing a decline of one birth in total fertility. Incremental costs added $1.92 per capita to the $6.80 per capita primary health care budget. The results demonstrate that low-cost community health and family planning services can have an impact on both fertility and mortality even under conditions of extreme poverty. Posting nurses to community locations where they provide basic curative and preventive care substantially reduces childhood mortality, accelerating attainment of child survival MDGs. Community volunteer approaches, however, have no such impact, challenging the child survival value of international investment in volunteer-based health programs. The results also demonstrated that extending access to contraceptive supplies alone fails to address the social costs of fertility regulation, a key goal of the 1994 Cairo Conference on Population and Development (ICPD). Effective deployment of volunteers and community mobilization strategies offsets the social constraints to contraceptive-method adoption. While volunteers had no impact on child survival, their role was crucial to achieving fertility impact. Navrongo research thus demonstrates that affordable and sustainable means of combining nurse services with volunteer action can accelerate attainment of both the ICPD and MDG agendas.

In 1998, also under a subagreement with the Council, the NHRC launched a five-year experimental project testing the effect of mobilizing communities to reduce the practice of female genital cutting (FGC). This project revealed ways in which traditional social institutions support the practice of FGC, pointing to potentially promising strategies for community-based interventions.

The Community-Based Health Planning and Services Initiative

When a replication project in the Volta Region demonstrated that the Navrongo service model could be transferred to a nonresearch setting, the Ghana Ministry of Health (MOH) adopted the CHFP as a model

for reforming community health and family planning services at a national level. In 1999 the MOH launched CHPS to accelerate implementation of the new health policy. By mid-2005, CHPS was fully operational in 20 districts and under development in nearly every other district of Ghana.

CHPS comprises national consensus-building mechanisms, a liaison program that arranges training opportunities for health management teams from regions where there is interest in CHPS, and a field program that develops CHPS demonstration capabilities in lead districts. Analysis of successive phases of the Ghana program development process demonstrates that national policy and programs in Ghana can be reformed successfully by scaling up experimental projects—an approach that may work in other African settings as well.

The CHFP Dissemination Unit, based at the NHRC, links CHPS to the CHFP, providing information, consultation, and training services that bridge the programs. The unit worked to promote effective implementation of CHPS and fostered communication aiming to improve health and family planning services in Ghana.

The Council's contribution to CHPS under the PCP3 focused on three areas: (1) systematic documentation of CHPS implementation, including its pace and barriers to progress; (2) technical assistance to develop a CHPS Secretariat to oversee the initiative; and (3) technical assistance to specific CHPS implementation and monitoring/evaluation activities.

Technical Assistance to the Navrongo Community Health and Family Planning Project and the Community-Based Health Planning and Services Initiative

Part of project Number/s: **04700**
Country/ies: Ghana
Technical Coord.: James F. Phillips
Period: January 1994 – August 2005
Objective: To provide technical support for and research on the activities of the Experimental Family Planning Studies in Rural Africa program.

Activity Description:

Note: This activity encompasses all Population Council technical assistance to the activities of the Experimental Family Planning Studies in Rural Africa program.

Since 1992, the Council has provided technical support to the Ghana Ministry of Health (MOH) to establish a field research station in a rural traditional district and to conduct an experimental study on the demographic impact of community health and family planning services. Originally launched as a pilot project in 1994, the Navrongo Community Health and Family Planning project (CHFP) had become a district-wide experiment by 1996. By 1998 preliminary evidence of the project's impact led the government of Ghana to adopt Navrongo as the model for primary health care in all the country's districts. The Council's Policy Research Division provides continuing technical support to research activities of the Navrongo experiment ("The Navrongo Community Health and Family Planning Project") and collaborative support to its dissemination program ("Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project"). Support is also provided to a reproductive health research program to test the hypothesis that the practice of female genital cutting (FGC) can be reduced through community outreach ("A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana").

In 1999 the Community-based Health Planning and Services initiative (CHPS) was created to coordinate the process of scaling-up the CHFP project. Council assistance focuses on systematically documenting the pace of and barriers to progress in CHPS implementation, and providing technical assistance to develop the CHPS Monitoring and Evaluation (M&E) Secretariat to oversee implementation and develop effective strategies to assess progress ("Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy").

Final Report:

From 1999 through 2005, the PCP3 funded technical assistance by Population Council staff for the following activities:

1. Conducting multi-level analyses of the Navrongo CHFP's impact on fertility, child survival, contraceptive use, and birth spacing patterns. Results from these analyses have been published in numerous peer-reviewed journals, including *Studies in Family Planning* and *Social Science and Medicine*, and have been collaboratively presented by the Navrongo Health Research Centre (NHRC) and Population Council staff at national and international conferences, including the Ghana National Health Forum, Annual Meetings of the Population Association of America, and the XXXIV and XXXV Conferences of the International Union for the Scientific Study of Population.

2. Designing and implementing operations research studies to assess strategies for implementing CHPS, disseminating lessons learned, and promoting the use of the study's findings to improve service delivery.

3. Convening international exchanges to promote the use of lessons learned from the CHFP and CHPS in other sub-Saharan African countries. In 2005, the NHRC played host to two international exchanges for health officials from the Ministries of Health of Burkina Faso, Ethiopia, and Sierra Leone. These exchanges aimed to develop a common understanding of the Navrongo experiment and its relevance to health policy development in the region, and provided a forum in which the visiting country teams could articulate their respective health service delivery needs. Additionally, the exchanges led to the formation of a network dedicated to applying evidence-based, problem-solving strategies for improving health services.

4. Population Council staff were intimately involved with designing, implementing, analyzing data, and disseminating findings from the Navrongo FGC Eradication Experiment. In addition, staff assisted the NHRC in investigating patterns of circumcision denial and the effect of this denial on measuring the impact of the intervention strategies. Results of this experiment have been published in *Studies in Family Planning*, and have been collaboratively presented by NHRC and Population Council staff at international conferences, including the Annual Meeting of the American Public Health Association and the Global Health Council Annual Conference.

5. Designing, testing, and refining the district-level evaluation survey (DES) to assess the impact of CHPS service delivery, and conducting and evaluating DES studies in Nkwanta and CHPS innovator districts.

6. Disseminating results from M&E research in peer-reviewed journals, including *Health Policy and Planning* and *The International Quarterly of Community Health Education*, and in presentations at national and international conferences, including at the Regional and District Directors of Health Services Annual Meeting, National Health Fora, the Global Health Council Annual Conference, and the Global Forum for Health Research Annual Meeting. Presentations were collaboratively made by the Ghana Health Service Policy Planning, Monitoring and Evaluation (PPME) Division and Population Council staff.

7. Funding specialists with expertise in multimedia to assist with video production for the CHFP unit for disseminating lessons learned; developing and upgrading websites and web design skills at the NHRC and CHPS M&E Secretariat; and editorial and production assistance for newsletters produced by the CHFP dissemination unit and the Nkwanta Health Development Centre.

8. Providing guidance with regards to administrative and financial reporting to USAID, the Ghana Health Service, the Population Council, and other CHPS stakeholders.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ghana Health Service
Ghana Ministry of Health (MOH)
INTRAH/PRIME II
John Hopkins University
Navrongo Health Research Centre (NHRC)

Activity Funding: Field Support & Pop Core

Contribution to Results Framework: IR 3.1

The Navrongo Community Health and Family Planning Project

Part of project Number/s: **04700**

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: January 1994 – June 2005

Objective: To test the hypothesis that fertility and child mortality rates can be reduced through community services in a rural setting in sub-Saharan Africa.

Activity Description:

Note: This activity is carried out through the Population Council's core-funded subaward to the Navrongo Health Research Centre (NHRC), which also supports "The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project" and "A Community-Informed Experiment in Preventing FGC Among the Kassena-Nankana of Northern Ghana."

For over three decades, there has been general consensus on the need to establish community health and family planning services in Africa, yet there is remarkably little sound scientific evidence that the strategies being pursued can reduce mortality and fertility. By the early 1990s, two broad approaches to health care were being advocated, one emphasizing the sustainability of volunteer efforts (the UNICEF-sponsored Bamako Initiative), and the other, the importance of professional paramedical care. The Community Health and Family Planning project (CHFP), fielded by the NHRC, was created to resolve this debate.

The Navrongo CHFP makes use of a four-celled experimental design. Each approach to health care is pursued independently in respective cells (volunteers only or nurses only), jointly in one cell (both volunteers and nurses), and not at all in a fourth cell, which retains the existing clinical program. Testing these hypotheses in Navrongo is particularly important for national and regional policy deliberations. The region in which the NHRC is located is the poorest and most remote in Ghana. Mortality is high, and women's educational attainment, autonomy, and authority are constrained by marital customs, family-building strategies, and patriarchal systems of gender stratification. If health and family planning services can work in such a setting, they can work anywhere.

By 1997, preliminary evidence from Navrongo suggested that the experimental interventions were having an impact. A single nurse equipped with a motorbike and relocated to a village health center could outperform the staff of an entire subdistrict health center. The volume of health service encounters in study areas increased eightfold, immunization coverage improved, and adoption of family planning increased dramatically. Results were evident in all experimental intervention cells, but the impact of the combined service strategy was particularly compelling.

Final Report:

CHFP results indicate that fertility within the study district has declined rapidly over the last decade, from 5 births per woman down to 3.9. While fertility has declined throughout the entire district, the decline has been more pronounced in areas where a health professional is present. On average, total fertility rates in the combined nurse-volunteer intervention cell were a full birth lower than fertility rates in the control cell.

Although childhood mortality rates have declined considerably over the last decade, they remain high in the Kassena-Nankana district (where Navrongo is located). This experiment resulted in significant gains in

childhood mortality reduction, as evidenced by the differences between the control and intervention cells. Because of the reductions in Navrongo, progress in attaining the child survival Millennium Development Goal (MDG) in Kassena-Nankana was accelerated, and in 2005 the child survival MDG was attained by the district. The largest gains in reduction of childhood mortality occurred in the nurse-only intervention cell, and in areas where community nurses had been posted, the MDG was attained by 2000. Volunteer services, however, had no impact on attaining the MDG, although they did have a positive impact on reproductive health.

Contraceptive use has risen throughout the district over the last decade. This increase has been the most dramatic and best sustained in the combined nurse-volunteer intervention cell. Regressions adjusting for other likely causes of the increase in contraceptive use found that, in the combined cell, educational attainment had a large effect on family planning and fertility outcomes, an association which was even stronger than anticipated. Even after controlling for education though, the extent of experimental impact was great enough to be able to declare the program a success.

Based on analysis of these outcomes, it was determined that the combined nurse-volunteer intervention is the most effective method of service delivery. Although the nurse-only deployment strategy had the greatest effect on reducing childhood mortality, the combined nurse-volunteer cell not only had a significant effect on mortality, but also had the greatest effect on reducing fertility and increasing contraceptive use. It is this combination of positive outcomes that led the CHFP team to determine that the nurse-volunteer deployment strategy was the most effective service delivery method.

Based on these results, the Government of Ghana in 1999 launched a process of transitioning to community-based health care delivery based on the Navrongo model, taking into account the adaptations developed in Nkwanta (see "Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative"). The new nationwide health service delivery model was to become known as the Community-based Health Planning and Service Initiative (CHPS).

With the CHFP model being implemented as part of the national health policy in 1999, the NHRC and its partners turned their attention to ways of transferring and adapting these evidence-based strategies to other countries in the region. In 2005, the NHRC played host to two international exchanges for health officials from three other sub-Saharan African countries. These exchanges aimed to develop a common understanding of the Navrongo experiment and its relevance to health policy development in the region, and provided a forum in which visiting country teams could articulate their respective health service delivery needs, and define and document a shared vision for future collaboration.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP01.02A)
Navrongo Health Research Centre (NHRC) (CP00.01A)
Population Council

Collaborating Organization(s): Ghana District Health Management Team
Ghana Health Service
Ghana Ministry of Health (MOH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project

Part of project Number/s: **04700**
Country/ies: Ghana
Technical Coord.: James F. Phillips
Period: November 2002 – June 2004
Objective: To provide accurate and timely data on demographic events for the Community Health and Family Planning project (CHFP).

Activity Description:

Note: This activity is being carried out through the Population Council's core-funded subaward to the Navrongo Health Research Centre (NHRC). The same subaward also supports "The Navrongo CHFP" and "A Community-Informed Experiment in Preventing FGC Among the Kassena-Nankana of Northern Ghana."

An international, interdisciplinary team of scientists has been working for nearly a decade to harness the power of computer technology to increase longitudinal health and population research capacity in developing countries. The common technical platform of these initiatives is a Council-developed computer software generator known as the Household Registration System (HRS), which was field-tested at the NHRC. HRS-generated systems now operate in 16 sites in research stations in Africa and Asia. Software code produced by the HRS serves as the electronic foundation of the Navrongo Demographic Surveillance System (NDSS). This system supports several scientific undertakings at the NHRC, including the Navrongo CHFP, by providing longitudinal data on the course of reproductive and survival changes in Kassena-Nankana District. Recent publications reporting on CHFP demographic impact are NDSS-based.

Financial support to develop and maintain the NDSS was provided by the Rockefeller Foundation, but this funding ended on 30 June 2002 because the foundation decided to end its population program. However, a new Rockefeller Foundation adolescent health initiative is now supporting half of the cost of the system. Other non-CHFP health protocols are funding an additional 30 percent of all NDSS costs. The remaining 20 percent of NDSS costs are borne by the CHFP. The funding is preserving the ability to continue surveillance operations within the Kassena-Nankana District, enabling the NHRC to sustain its general research program, and facilitating CHFP impact assessment. USAID initially allocated core funds to support operation of the NDSS components that feed directly into the CHFP experiment (i.e., that provide the fertility and mortality data linked with the CHFP's annual panel survey) in Year Three of the Population Council Program III (PCP3). However, those funds were not used during Year Three because sufficient funds were available from the Rockefeller grant.

Final Report:

Support to the NDSS by USAID has been critical to ongoing analysis of the fertility and mortality impact of the CHFP. In particular, the NDSS was used by NHRC researchers to assess the affect of mortality decline on reproductive change. The hypothesis was that high fertility in high mortality settings is influenced by the tendency of couples to replace children who have died. Birth and deaths data occurring to children of 43,000 women observed in the NDSS over the July 1993 to June 2003 period was analyzed. Results show that child spacing customs may accompany child mortality rather than child replacement. Thus, the fertility impact of child replacement behavior is offset by child spacing customs. Themes from

this research have been incorporated into various communication mechanisms of the Community-based Health Planning and Services (CHPS) Initiative so that results are linked to Ghana's health policy and program development activities.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP01.02A)

Collaborating Organization(s): Ghana Health Service
Ghana Ministry of Health (MOH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project

Part of project Number/s: 06613

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: January 1997 – August 2004

Objective: To orient teams of visitors to the Navrongo Community Health and Family Planning project (CHFP) system of service delivery and to provide support to the national CHFP scaling-up program, known as the Community-based Health Planning and Services initiative (CHPS).

Activity Description:

Note: This activity is carried out through the Population Council's field support-funded subaward to the Dissemination Unit of the Navrongo Health Research Centre (NHRC).

In January 1997, the NHRC began to develop a full-scale effort to disseminate information about the processes and findings of the CHFP experiment through hosting site visits and presenting at national and international conferences and forums. Positive feedback from the preliminary results of the CHFP experiment during the period 1996 through 2000 led the Ghana Ministry of Health (MOH) to develop the lessons learned from the project into the CHPS initiative for delivering health care to communities throughout the country. The MOH called upon the NHRC to use its experience implementing and maintaining the CHFP to facilitate the participation of other Ghanaian and outside agencies in the scaling-up process. In October 1999, the Council issued a subaward to the NHRC for the purpose of funding the dissemination activities, including developing materials for training and sharing lessons learned, and providing training (both on-site and at the NHRC) for health professionals implementing CHPS in other regions of Ghana. In addition, the subaward provided a mechanism through which the NHRC could convene CHPS regional and national dissemination conferences, as well as play a role in establishing a CHPS Secretariat at the Ghana Health Service (GHS) in Accra to guide the nationwide CHPS initiative.

Final Report:

Throughout the life of the project, CHFP Dissemination Unit staff represented the CHFP at CHPS partners meetings convened by the GHS and the USAID Mission. The NHRC coordinated and participated in a series of meetings with policymakers to inform them on the CHFP strategy and to gain consensus on CHPS, the nationwide scaling up of the CHFP experiment. These efforts included convening a district directors conference in Cape Coast in 2000, co-coordinating a national health forum on CHPS in 1999, and participating in another national health forum in 2003. Also in 2003, the Dissemination Unit collaborated with the CHPS Monitoring and Evaluation (M&E) Secretariat to convene a workshop for advanced CHPS districts interested in sharing their experiences with other districts implementing CHPS. In addition, the NHRC conducted field exchanges to train implementing districts in theoretical and practical processes. In all, representatives from 28 districts throughout Ghana visited Navrongo, and Dissemination Unit staff made 12 visits to implementing districts to assess progress and provide guidance on implementation.

The CHFP Dissemination Unit served as the interim CHPS M&E Secretariat for the GHS from 1999 through 2000, coordinating national consensus-building activities and helping develop a system for the nationwide scaling up of the CHFP service delivery model. In 2001, this function was transferred to the Policy Planning, Monitoring and Evaluation (PPME) Division of the GHS (see "Establishing a Community-

Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy").

In July 2001, the CHFP launched a collaborative program of documentation and dissemination with the Kassena-Nankana District Health Management Team (DHMT) to produce a series of newsletters entitled "What Works? What Fails?" The series described the CHFP experiences and results in order to provide training materials for CHPS districts. A total of 84 newsletters were completed and distributed. Another series, "Pogsara Yia!" ("Girls First!"), was launched in July 2001. The focus of this series was to inform interested parties about the FGC Eradication Experiment activities (see "A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana"). Sixteen issues were published. Both series have been distributed to the Regional Health Offices, to the Directorates of the MOH and GHS, and to donor and other interested parties in the international arena. In August 2004, the Dissemination Unit published a bound edition of each newsletter series for use in the CHPS-Technical Assistance (CHPS-TA) Cooperative Agreement and by those interested in promoting CHPS throughout Africa.

The Dissemination Unit was instrumental in promoting CHPS processes through pre-service training programs. Consultations and field exchanges were held with the Tamale Community Training School, the Kintampo Rural Health Training School, the Bolgatanga Upper East Regional Health Training Centre, and the Bawku Health Training Center, among others. In addition, the NHRC provided technical assistance for the creation of, and instruction at, the Navrongo Community Health Nurse Training School (CHNTS), established in 2002. Staff involved in the school's development have been collaborating closely with CHPS-TA staff on the pre-service training program. In 2005, an operations research study was conducted jointly by the NHRC and CHPS-TA to compare the Navrongo CHNTS model for pre-service training with the more traditional structure at the Tamale CHNTS.

The Dissemination Unit produced five videos over the life of the project: 1) *Male Involvement in Family Planning*; 2) *Who's mutilating our women? A documentary of FGM*; 3) *Volunteerism – The life and work of a Community Health Volunteer* ; 4) *The Community Health Officer – The life and work of a CHO*; and, 5) *The Navrongo Day Community Health Nurse Training School* . The first two videos focused on the CHFP and FGC experiments and were used for community dissemination, and the other three were used as training material for DHMTs coming to the NHRC for CHPS orientation.

The work of the Dissemination Unit was deemed essential to CHPS stakeholders' efforts to explain and promote the Navrongo model. Since the end of the subaward, NHRC staff have continued their mission; they have coordinated local end-of-project workshops for the CHFP and FGC experiments, and have co-hosted two field exchanges to promote the adoption of the Navrongo model in four other sub-Saharan African nations. Unfortunately, insufficient funding has limited the extent to which the Dissemination Unit can play an ongoing role in the process of disseminating lessons learned from the CHFP project.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP99.06A)

Collaborating Organization(s): Ghana Health Service

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana

Part of project Number/s: **04700**

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: April 1998 – June 2005

Objective: To implement a full-scale experimental program to prevent female genital cutting (FGC), continue surveillance of FGC prevalence, conduct research to enhance understanding of issues contributing to changes in FGC behavior, and assess the impact of the program.

Activity Description:

This experimental study tests the hypothesis that female genital cutting (FGC) can be reduced by community organization and action in a setting where the practice has been nearly universal. Between 1995 and 1998, CHFP researchers identified a complex system of support for the practice of FGC that was ingrained in traditional social values and involved all members of society and social strata. A program of "participatory planning" was used to guide development of the intervention with a special focus on women, who were found to be the most active proponents of FGC. Two distinct strategies were developed: (1) education about the harmful effects of FGC, and (2) empowerment of women and girls through increased economic opportunities, livelihood skills, and development strategies. The two intervention arms are coordinated as a single factorial design; the two arms of the initiative are implemented independently in two cells, jointly in one cell, and not at all in the fourth, control cell. Pilot intervention program activities, completed in October 2000, tested these strategies and clarified ways to mobilize community support and reach all actors in the FGC system.

Final Report:

In 1999, a baseline survey of 3,221 adolescent girls aged 12-19 was conducted which collected information on FGC prevalence, background characteristics, and attitudes and beliefs about the practice of FGC. The 12-19 age cohort was chosen because it contained those girls most at risk of circumcision. In order to document changes in the age-specific incidence of FGC, adolescents aged 12-19 were interviewed annually until the final survey in 2003. A survey similar to the baseline was administered in 2000 and 2001, and abbreviated surveys were administered in 2002 and 2003. In 2000 and 2001, only those previously-surveyed girls who were currently aged 12-19 were re-interviewed, while in 2002 and 2003, all previously-surveyed girls were interviewed, even if they were currently older than 19. In 2002, another comparison area comprising 1,073 girls was surveyed, and retrospective data on FGC status and date of circumcision (if applicable) were collected.

Overall, in 2000, 3,018 girls were interviewed; in 2001, 3,120 were interviewed; in 2002, 4,886 were interviewed; and in 2003, 4,686 were interviewed. The annual surveys were linked to assess circumcision incidence rates. In the new comparison area, incidence rates were determined using the circumcision dates provided by the girls. High rates of denial of previously-reported circumcisions resulted in inaccuracies in the annually-adjusted FGC prevalence rate; these inaccuracies were corrected during data analysis.

The data showed that FGC prevalence is not uniform throughout the study area; the survey baseline in 1999 showed FGC prevalence ranging from 4 to 24 percent across the four study cells. Cross-sectional analysis

of FGC prevalence by experimental exposure showed that overall decreases in prevalence occurred in both the experimental areas and the comparison area, and that overall prevalence fell greatly in some experimental areas before exposure had even occurred.

Quantitative and qualitative analyses were conducted to assess the impact of denial of circumcision on the intervention's measured outcomes. These analyses led to the conclusion that denial of having experienced FGC had no relation to the type of intervention to which a person was exposed. Additionally, the analyses revealed some important attitudes and perceptions concerning the issue of circumcision. The qualitative findings in particular pointed to a number of complex factors influencing denial. Most striking was the fact that girls were uncertain about the rationale behind the questions and thus apprehensive about the potential consequences of their responses. Awareness of the law banning the practice is high, so many feared the risk of arrest. In addition, mockery and ridicule is now being directed toward those who circumcise. All these changes have caused circumcised girls to regret their circumcision, and thus feel sad, angry, or embarrassed when being questioned about it.

Results revealed that exposure to problem-focused FGC education strategies, where circumcision is openly identified as an issue worthy of community action, education, and prevention, was associated with a 93 percent decreased incidence of FGC relative to no intervention exposure; and that exposure to education and to livelihood and development strategies together was associated with a 94 percent decreased risk of circumcision relative to no exposure. Taken individually, the education strategies had a significant effect, while the livelihood and development strategies by themselves had no appreciable effect.

Based on this evidence, the NHRC, with technical assistance from the Population Council, scaled up the intervention to all areas of the Kassena-Nankana District. While only the education strategies were found to be statistically effective, the livelihood and development strategies were also included as they are considered beneficial for reasons other than FGC incidence reduction. The scale-up occurred over a 12 month period (January – December 2004); the final status report on the scale-up is forthcoming.

The NHRC would like to perform an assessment of the impact of this scale-up, however no funding is currently available for this effort.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP02.11A)
Navrongo Health Research Centre (NHRC) (CP01.02A)
Navrongo Health Research Centre (NHRC) (CP00.01A)

Collaborating Organization(s): ACTIONAID Ghana
Center for Sustainable Development
Ghana Association of Women's Welfare
Ghana District Health Management Team
Ghana Health Service
Ghana Ministry of Health (MOH)
National Commission on Women and Development

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Conference to Advance Research on Female Genital Cutting

Project Number/s: **04701**
Country/ies: Italy
Technical Coord.: James F. Phillips
Period: April 2002 – July 2002
Objective: To provide a forum for the exchange of scientific knowledge on the causes, consequences, and abandonment of female genital cutting (FGC).

Activity Description:

In response to the relative dearth of research to support efforts against FGC, Population Council senior staff, along with Council consultants, set out to identify means to promote research on FGC and facilitate the translation of research findings into action. The committee obtained support to conduct the following activities in order to realize these goals: (1) convene a conference of FGC researchers from various disciplines and geographic areas; (2) compile, edit, and publish a monograph on FGC research; and (3) launch a formal network to advance research on FGC and the dissemination of research findings. The committee obtained funding from the Rockefeller Foundation's Bellagio Fund to host a conference at the Bellagio Study and Conference Center in Italy in the spring of 2002 and to provide travel funds for participants from developing countries. The Rockefeller Foundation's Africa Regional Program provided funds for the production of preconference materials and conference output. The Population Council Program III provided support for the travel of participants from developed countries to the conference site, and for the consulting fees of two conference coordinators.

Final Report:

The Population Council, with the support of the Rockefeller Foundation and USAID, convened twenty social scientists and program planners at the Conference to Advance Research on Female Genital Cutting (FGC) in Bellagio, Italy, 29 April–3 May 2002. The conference was successful in providing an initial forum for the exchange of scientific knowledge on the causes, consequences, and abandonment of FGC. Perhaps more importantly, the participants have remained active in planning for the compilation of a monograph that will include papers outlining the current state of knowledge and areas for future research; preparing a paper outlining a research agenda that will fill important gaps in knowledge; and launching a network that would have as its mission promoting research on FGC and the dissemination of research findings to relevant audiences. Ongoing dialogue with representatives of the international development community have revealed strong interest in supporting the initiative launched at Bellagio.

At the conference an interdisciplinary group of highly qualified social scientists and program planners presented key findings in their respective areas of work. A subset of the conference participants was commissioned to submit papers for publication in a monograph, and a publications committee was established to oversee production of the issue. Conference participants reached a consensus on the broad mission and initial plan of action for an FGC research network, and organized a committee to initiate activities to launch the network.

Postconference activities have included preparing a founding document for the proposed FGC research network; presenting conference findings, including a summary of knowledge and proposed research agenda, at the annual meeting of the Population Association of America in May 2003; establishing a Web site (www.INTACT-Network.net) that will provide a medium for the network to communicate research

findings and program results to a wide audience; preparing papers for publication ("The social correlates of denial of female genital mutilation among women in the Kassena-Nankana District of northern Ghana" was recently accepted by *Studies in Family Planning*); and preparing a funding proposal for the expansion of the INTACT network for submission to USAID and WHO.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy

Part of project Number/s: **06613**
Country/ies: Ghana
Technical Coord.: James F. Phillips, Ellie Feinglass
Period: October 2002 - July 2005
Objective: To develop a Community-based Health Planning and Services initiative (CHPS) M&E Secretariat and to design and implement a CHPS M&E system nationwide.

Activity Description:

Note: This activity comprises one part of the Population Council's support for CHPS implementation.

In 1994, the Navrongo Community Health and Family Planning (CHFP) Experiment commenced, and evidence that the experiment was having a significant impact led the Government of Ghana in 1999 to launch a process of transitioning to community-based health care delivery countrywide. The new nationwide health service delivery model was to become known as the Community-based Health Planning and Service Initiative (CHPS). The recently established Ghana Health Service (GHS) began working with Regional and District Health Management Teams to implement CHPS. The GHS decided that a secretariat would be established to oversee implementation strategies and conduct monitoring and evaluation (M&E) activities to ensure these strategies were effective. The Navrongo Health Research Centre's CHFP Dissemination Unit was designated as the interim Secretariat, and funds were allocated through a subaward to support operations (see "Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project"). In 2001, the GHS established a permanent Secretariat based in its Policy Planning, Monitoring, and Evaluation (PPME) Division, and later that year, the Council issued a subaward to PPME to establish systems for monitoring and evaluating the pace of, constraints to, and impact of CHPS implementation on health service outputs and health behavior.

Final Report:

The CHPS Monitoring and Evaluation (M&E) Secretariat has developed four main M&E tools to assess CHPS: the M&E database, qualitative system assessments, demographic impact surveys, and a website.

The Secretariat collects data quarterly from Regional and District Health Management on CHPS implementation throughout the country. Key findings of the Secretariat are as follows: (1) the majority of districts (110/138) have started the CHPS implementation process; (2) an implementation gap exists between districts, that is, many districts have not moved beyond the planning stage; and (3) only nine districts have established one or more zones where CHPS implementation is complete. These findings have been used to devise strategies to bridge the gaps in implementation and allow for the establishment of a greater number of fully-functional CHPS zones. Some of these strategies are being tested in partnership with USAID/Ghana and the Council's CHPS-Technical Assistance (CHPS-TA) Cooperative Agreement.

In four of Ghana's ten regions, the Secretariat has conducted qualitative assessments with CHPS workers, whose opinions are viewed as essential for understanding challenges the system faces on the front line, to gauge CHPS' strengths and weaknesses. The surveys have provided positive feedback to stakeholders: communities are enthusiastic about the program, and, while clinic nurses are initially apprehensive about CHPS, they adjust well to the rigors of community-based work once posted to a community. Further,

workers recognize the need for counterpart training, thus validating the importance of field exchanges, a central element of the CHFP Dissemination Unit's training strategy. Results also show how a District Assembly that is actively engaged by CHPS workers can effectively mobilize additional resources.

CHPS demographic impact surveys (developed by PPME with technical assistance from Council staff) which measure the number of people receiving treatment, family planning users, women receiving safe motherhood services, and children being immunized, have been conducted in five districts. Three district surveys have been completed and data from the other two districts are currently being analyzed. Results thus far have demonstrated that CHPS has a positive impact on all the above-mentioned indicators.

The Secretariat has created a website: www.ghana-chps.org. The site is used to share information on CHPS history, processes, and implementation progress, and to disseminate research findings.

Additionally, in 2002, the Secretariat established a 12-member PPME Awards Task Force which granted six subawards between 2002 and 2005 to district health programs using innovative CHPS implementation activities. Key findings were as follows: *Abura Asebu Kwamankese (AAK):* District Assemblies can be mobilized to garner outside financial support for CHPS; *Birim North:* Intensive efforts at community mobilization can greatly increase the number of fully-functioning CHPS zones established within a district; *Bawku West:* Using advanced CHPS communities to guide newly-implementing ones can lead to more sustainable CHPS expansion; *Jasikan:* Community entry using trained facilitators can result in greater community acceptance of CHPS; *Juabeso Bia:* Private practitioners can be integrated into CHPS systems, thus expanding CHPS coverage areas; *Saboba Chereponi:* Males and local residents can be community health officers (CHOs) who are both effective in and accepted by their communities.

Support to PPME is continuing under the CHPS-TA Cooperative Agreement. Improving routine data collection and upgrading the CHPS website are priority items for the new project. In addition, CHPS-TA has issued follow-on subawards to three of the innovator districts —AAK, Birim North, and Juabeso Bia — so that they can serve as demonstration sites for newly-implementing districts.

Implementing Organization(s): Upper East Region Health Administration (CP04.05A)
Western Region Health Administration (CP04.04A)
Northern Region Health Administration (CP04.03A)
Volta Regional Health Administration (CP04.02A)
Ghana Health Service; Policy Planning, Monitoring, and Evaluation (PPME) Unit (CP04.01A)
Eastern Region Health Administration (CP03.08A)
Central Region Health Administration (CP03.04A)
Regional Institute for Population Studies (CP02.10A)
Ghana Health Service; Policy Planning, Monitoring, and Evaluation (PPME) Unit (CP02.06A)
Ghana Health Service; Policy Planning, Monitoring, and Evaluation (PPME) Unit (CP01.06A)

Collaborating Organization(s): Ghana Health Service

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative

Part of project Number/s: **06613**
Country/ies: Ghana
Technical Coord.: James F. Phillips, Ellie Feinglass
Period: July 2001 – August 2004
Objective: To develop a Community-based Health Planning and Services initiative (CHPS) "lead district" that can serve as a model for organizational change in the national health care program.

Activity Description:

Note: This activity comprises one part of the Population Council's support for CHPS implementation.

By 1996, encouraging results from the Community Health and Family Planning project (CHFP) (see "The Navrongo Community Health and Family Planning Project") began to emerge. The methodology of community dialogue and mobilization was being clarified and the beginnings of meaningful community participation in health planning and services were taking shape. Subsequent developments and research over the next four years confirmed the initial findings and outlined definitive impact, which were presented to the Ghana Ministry of Health (MOH) and other stakeholders in a series of seminars and meetings. Further deliberations on the findings at the policy level led to the acceptance of a national initiative for scaling up the CHFP experiment.

The first phase of this effort, known as the Community-based Health Service Delivery initiative (CHSD), began in 1997 in Nkwanta District. In a pioneering move, Nkwanta modeled its service delivery strategies on the CHFP experience, with spectacular results. With Nkwanta taking the lead, the CHSD became the major mechanism for resolving the national problem of accessibility to health care.

Based on this success, the MOH launched sector-wide health reforms aimed at improving access, equity, efficiency, quality, and sustainability of health and family planning services throughout Ghana. This program — the Community-based Health Planning and Services initiative (CHPS) — was launched in 1999. CHPS calls for "lead districts" to be developed in each of Ghana's ten regions, in which adaptations of the CHFP system are tried, refined, and adapted to local realities and needs. Lead districts, in turn, become demonstration areas for operational change in other districts. The Council has used its field support from USAID to award funds to Nkwanta District to develop a lead district strategy that can serve as a model for demonstrating and fostering operational and organizational change in the national health program.

Final Report:

In 2002, the Nkwanta District Health Management Team (DHMT) conducted the pilot District-level Evaluation Survey (DES) and created a toolkit for using the DES methodology in other CHPS districts (see "Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy"). In 2004, to assess whether any changes in health-seeking behavior had occurred and whether CHPS was continuing to have an impact on health indicators, a follow-up survey was conducted, which included a more detailed section on HIV/AIDS and a series of questions regarding migration behavior. With the financial support of the Mellon Foundation, XFP project staff provided Nkwanta with technical assistance to finish this important task.

Results from the 2002 DES demonstrated that children living in areas exposed to CHPS were 1.6 times more likely to be immunized than children not exposed. CHPS also had a positive impact on child health record keeping; regression analysis showed that children in CHPS areas were over two times more likely to have a health card. Within CHPS zones, 65 percent of CHPS children aged 12-24 months at the time of the survey were fully immunized.

Assessment of standard CHPS indicators in the 2004 DES demonstrates program success. First, family planning usage district-wide increased from less than 4 percent pre-CHPS to 8.6 percent in 2004. Differentials by CHPS exposure illustrate that within CHPS zones, family planning usage was 14 percent, which, while low, was three times higher than that in areas not yet exposed to the CHPS initiative. Second, the odds of having received antenatal care were more than five times greater in CHPS zones compared with control areas, and the odds of receiving antenatal and postnatal care were two to three times greater among women exposed to CHPS than women living near medical services. And third, the odds of completing the polio immunization series were 2.8 times greater in children who had a Community Health Officer (CHO) residing within their community than those living in comparison areas, and, overall, the odds of being fully immunized were 2.4 times greater among children living in CHPS areas than in control areas.

A very important finding from the 2004 DES was that CHPS diminishes the relationship between distance to facility and health indicators. For example, not only is the contraceptive prevalence rate (CPR) higher where CHPS is operating, but there is no difference in CPR between those residing close to the health compound and those in remote locales.

Between 2002 and 2004, the Nkwanta team produced a series of newsletters entitled “Putting Success to Work,” which complemented the efforts of the NHRC to disseminate lessons learned and provide practical guidance to CHPS-implementing districts throughout Ghana. Nkwanta produced and distributed 13 issues.

Finally, field exchange visits were conducted with 18 implementing CHPS districts between 2001 and 2004. On-site training facilities were upgraded to allow for comprehensive practical skills training as well as classroom instruction. Follow-up visits to monitor progress were conducted by the CHPS M&E Secretariat. This series of field exchanges is continuing through funding provided by the new CHPS-Technical Assistance (CHPS-TA) Cooperative Agreement.

By the end August 2004, the Nkwanta District had 16 CHPS zones established — eight fully functioning, three in progress with no CHO deployed, and five in the initial planning phases. The DHMT continues to implement CHPS district-wide, with technical assistance provided by CHPS-TA.

Implementing Organization(s): Volta Regional Health Administration (CP02.02A)
Volta Regional Health Administration (CP01.03A)

Collaborating Organization(s): Ghana Health Service; Policy Planning, Monitoring, and Evaluation (PPME) Unit

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Subaward to the University of Cape Coast for Assessing Demographic Impact of the Community-Based Health Planning and Services Initiative

Part of project Number/s: **04700**
Country/ies: Ghana
Technical Coord.: James F. Phillips, John Casterline
Period: July 2002 – June 2003
Objective: To assess the impact of Community-Based Health Planning and Services initiative (CHPS) program exposure on social interaction about family planning and reproductive behavior.

Activity Description:
Note: This activity comprises one part of the Population Council's support for CHPS implementation.

Beginning in 1998 a survey examining the association between social organization and reproductive behavior has been conducted in three regions of southern Ghana in collaboration with the University of Cape Coast and with support from the National Institutes of Health. During the latest round of survey data collection, conducted from September 2001 to December 2002, a new section titled the "Health and Family Planning Services Module" was added, its purpose being to serve as a baseline for the study of the potential impact of CHPS initiative exposure on social interaction about family planning and reproductive behavior in the communities in question. The Population Council Program III partially supported this section of the latest round.

By aligning the CHPS assessment with the ongoing research, the Monitoring and Evaluation Secretariat will have an exceptional opportunity to learn about the types of people who respond positively to CHPS, the kinds of pre-existing reproductive health needs that CHPS satisfies, and the channels through which CHPS reaches into communities and modifies attitudes and behaviors. The basic design was to be quasi-experimental, with pre- and post-intervention measurements.

The principal objectives of the proposed research were: (1) to track the spread of awareness of CHPS and attitudes toward CHPS in a set of selected communities in Central and Western Regions of Ghana, and to compare these with awareness and attitudes toward health and family planning services in other communities in Greater Accra, Central, and Western Regions; (2) to determine the types of women and men who take advantage of the new services offered under CHPS and, in particular, the extent to which CHPS addresses pre-existing unmet need for family planning and other reproductive health needs; and (3) to monitor the way social interaction patterns and mass media exposure positively reinforce the impact of CHPS or, on the contrary, work against the desired aims of CHPS.

While it was the intention of the study team to conduct a post-intervention survey round during Year Five of the Population Council Program III, efforts to obtain additional funding for the overall study have not been successful. Nevertheless, researchers are confident the information obtained from the six communities during Year Four will inform CHPS program implementation.

Final Report:
Attitudes and experiences measured in the "Health and Family Planning Services Module" may have implications for the implementation of CHPS. Data collection took place in six study communities among

approximately 1,300 women ages 18–44 and their 800 male partners. When asked for their views on health service organization, the majority of respondents (62 and 64 percent, respectively) state that ownership and management of health services by the Ministry of Health (MOH) was preferred to both community and private control. Therefore, it would seem advisable to emphasize that CHPS is implemented under the auspices of the MOH. In addition, 82 percent of respondents prefer to visit a fixed health center rather than being visited at home, highlighting the need to build and maintain easy-to-reach health facilities. But while fixed health centers are preferred, there is much room to improve the effectiveness of home visits. Despite the fact that 56 percent of respondents report a home visit by a health provider during the past year, one-third of these visits did not result in the provision of medical supplies or services. On this score there are marked differences among the six study communities, varying from 96 percent of respondents in one community reporting that they were provided with supplies and/or services to only 50 percent in other communities. When asked questions regarding malaria, diarrhea, and persistent cough, the majority of respondents said they initially sought medical help at drugstores, but ultimately more than 75 percent of respondents did not seek further assistance from another source, such as a trained healthcare professional The implications of this information for CHPS are twofold: CHPS can fill the present gap in health care availability, and because drugstores are prominent sources of information for respondents, pharmacists should serve key roles in informing villagers of the presence of CHPS. While a consistent 85 percent of those from the Central and Greater Accra Regions know where to obtain birth control (in the form of condoms, pill, and injectables), this figure decreases to 70 percent in the Western Region. This finding indicates that the western districts of Ghana are most in need of access to reproductive health care.

Implementing Organization(s): University of Cape Coast (CP02.04A)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Understanding and Meeting the Needs of Adolescents

Program Summary

The Population Council's program of research on transitions to adulthood in developing countries seeks to better understand adolescents' lives and to identify, design, and test various interventions to increase opportunities and reduce risks for adolescents, particularly girls. The ultimate goal is to allow adolescents to emerge as reproductively healthy adults with productive skills that will permit them to be full participants in work, family, and community life. USAID through the Population Council Program III partially supported research on adolescents in Bangladesh, India, Kenya, Malawi and South Africa.

Evaluation of Interventions

The projects in Bangladesh, India, and South Africa assess the impact of new programs designed to affect the timing of marriage and childbearing and improve adolescent reproductive health. The objective is to identify policy interventions that will delay marriage and childbearing sufficiently to create the space in which more "successful" transitions to adulthood can occur, and at the same time contribute to filling that space with investments in improved capacities.

Bangladesh. This project studied the impact of two large-scale interventions, in order to explore how adolescents can improve control over decisions that are consequential to their lives, such as schooling and marriage.

The first study assessed the impact of educational incentive schemes introduced in 1994 for children and adolescent girls. Data from 2000 and 2001 confirmed that school enrolment increased more for girls than for boys, but also indicated that the risk of dropping out of school remained strongly differentiated by gender and class. Boys in poor households are more likely to drop out than boys in non-poor households, and all girls face similar and high risks of dropping out because of marriage. The study also found that while school programs are successful at encouraging unmarried girls to remain in school and increase the mobility of girls in general, marriage continues to take place at early ages. Girls continue in school until they marry but do not necessarily delay marriage for school. In addition, dowry payments are a menacing concern for parents, and early marriage is encouraged by perceptions that older girls will require higher dowries.

The second study evaluated an intervention program, which applied lessons learned from the previous 2000 study in three rural districts. The intervention provides adolescent girls who are recent school graduates with life-skills and livelihood training; subsequently, some girls are linked with existing savings and credit facilities; and entrepreneurship development and internship opportunities in the local communities are supported.

A baseline survey was conducted in 2001 in 90 villages and a follow-up survey was conducted in 2003 in 68 of the villages. The study showed that programs designed to give adolescent girls access to public spaces of their own, life-skills and reproductive health training, and livelihood training can have far-reaching effects; these programs encourage increased schooling, increased income and work, and delayed marriage. The study also documented who among the rural residents are most likely to join and maintain program membership. Although programs are more likely to be used by more educated households, this selectivity is compensated because these programs appeared to be taken up with most enthusiasm in the poorest and least educated district.

While the intervention encouraged delayed marriage, it did not specifically discourage dowry payment. A negative finding of the study is that most of those who delayed marriage appear to have paid higher dowry. Families of girls perceive and believe paying dowry is a strategy to ensure the well-being of their daughters, despite the fact that those who marry without dowry are found to suffer less abuse and enjoy more leisure during the early years of marriage.

Several important policy decisions have been influenced by the study. First, a national adolescent survey is underway to identify vulnerable areas and populations. Second, the Population Council is working with implementing agencies to incorporate strategies to address the question of dowry into programs to empower adolescent girls. Third, new programs are being developed to provide age- and need-appropriate interventions to improve livelihood opportunities.

India. This project contributed to the evaluation component of an intervention study in which the Population Council, in collaboration with CARE India, tested the feasibility and impact of adding four additional components to a reproductive health project in urban slum areas of Allahabad, Uttar Pradesh: (1) counseling about savings formation and livelihoods; (2) training in vocational skills; (3) assistance in opening savings accounts; and (4) follow-up support. Using a quasi-experimental pre- and post-test design that contrasted the experimental group with a comparison group of adolescents, the project investigated whether the intervention (1) increased girls' physical mobility and contact with individuals outside the family; (2) enhanced girls' skills development and sustained use of these skills; (3) altered work aspirations of girls and encouraged more progressive gender role norms; (4) reduced gender differentials in time use; and (5) increased girls' reproductive health knowledge.

Analysis of the 2003 endline data in combination with the 2001 baseline data indicated that although the livelihoods program was acceptable to parents and feasible to implement, the project had only a minimal impact on the behavior and attitudes of adolescent girls in the experimental slums. The greatest changes between the baseline and the endline surveys were found in those outcomes that most closely reflected the content of the intervention. Girls in the intervention group were significantly more likely to have knowledge of safe spaces, be a member of a group, score higher on the social skills index, be informed about reproductive health, and spend time on leisure activities than the matched control respondents. No effect was found on gender role attitudes, mobility, self-esteem, work expectations, time use, or labor market work, likely because of the short duration of the intervention, as well as the limited number of times that groups convened. Those designing future livelihood interventions with adolescent girls are advised to extend the period of time spent on group formation, negotiation and social skills, and vocational skill development.

South Africa. This project supported some of the research personnel for a longitudinal study of youth conducted in KwaZulu-Natal, South Africa, the province hardest hit by the HIV/AIDS epidemic. Wave 1 was fielded in 1999; wave 2 in 2001. The project included interviews with young people and their parents; community surveys examining infrastructure, services, and safety; and interviews with secondary school principals to assess the extent of coverage of the government-mandated school-based life-skills curriculum and its impact on the sexual risk-taking behaviors of young people. As the first panel study of adolescents in the country, it is filling important gaps in knowledge about the determinants of adolescent risky sexual behavior and educational attainment in an environment characterized by both high HIV prevalence and highly unequal access to opportunities and services, including schooling, employment, and health care.

Research results indicate that poverty is associated with earlier sexual debut. Among females, poverty increases the risk of nonconsensual sex, having traded sex for goods or favors, having multiple sexual partners in the year before the survey, and teenage pregnancy.

Evaluation of the school-based life-skills curriculum reveals that coverage is rapidly increasing; knowledge about HIV prevention topics is increasing, particularly among Africans, males, and younger people; and youth exposed to the life-skills curriculum are more likely to use condoms.

Asessment of Computer Interviewing

The projects in Kenya and Malawi assess a new technique designed to improve the accuracy of the data collected on adolescent sexual and reproductive behavior. Inaccurate reports of sexual behavior affect explanations about the underlying mechanism driving the HIV epidemic and therefore intervention strategies to reduce transmission; they also provide a misleading picture of HIV/STI risk. Accurate self-reporting is also essential for clinical trials that investigate the effectiveness of technologies to prevent transmission of HIV and other sexually transmitted infections.

Kenya. In a study conducted in two districts in Kenya—Nyeri in Central Province and Kisumu in Nyanza Province—more than 6,000 interviews of unmarried adolescents ages 15–21 were collected as part of household-based surveys in 2000 and 2002. Respondents were randomly assigned to three modes of data collection: face-to-face interviews, paper-and-pencil self-administered interviews, and audio computer-assisted self-interviews (audio-CASI). The purpose of this experimental design was to assess the feasibility of computerized interviewing in Africa and to evaluate whether the increased privacy afforded by ACASI produced differential reporting of sensitive behaviors.

The ACASI technology performed quite well, despite the rigorous conditions of working in a rural area among a population largely unfamiliar with computer technology. Given the limited number of problems experienced with the ACASI software or computer hardware, and the positive response from respondents, our experience indicates that computerized interviewing is a feasible method of collecting survey data in developing countries.

Results indicate substantial and significant differences in reported rates of sex across interview modes, although not always in the expected direction. Our assumption that girls under-report sexual activity in face-to-face interviews by comparison with ACASI was not confirmed by the Nyeri data, while the Kisumu results show ACASI generated significantly higher levels of reporting of sensitive behavior among girls. As for boys, results from Kisumu, while not always significant, show reporting for the "ever had sex question" is lower with ACASI whereas reporting of more stigmatized behaviors is higher with the computer, as was expected.

Analysis of data indicated that ACASI produced a more diverse picture of adolescent sexual activity than the face-to-face interviewer-administered method. The analysis suggests that adolescent girls in Kenya have more complicated, and clearly more perilous, sex lives than traditional surveys of sexual activity indicate. With ACASI, a much wider range of sexual partners is revealed and a much higher incidence of coerced sex is observed than with face-to-face interviews.

Malawi. Given the promising results from the Kenya study, the research program on assessing and improving the measurement of sexual behavior is expanding. In collaboration with researchers at the

University of Pennsylvania, a household-based survey of female adolescents took place in Malawi in May and June 2004. Five hundred adolescent girls aged 15–21 were randomized to face-to-face and ACASI interviews. As in Kenya ACASI did not result in higher reporting for questions on "ever had sex" and "sex with a boyfriend;" however, it did produce higher reporting for more stigmatizing behaviors such as sex with a family member or teacher. Although the comparability of results across two countries provides a sense of reliability regarding the findings, it does not explain the inconsistent response patterns. Clearly more research is required to assess these issues.

Patterns of Marriage and the Onset of Childbearing in Rural Bangladesh: The Impact of Large-Scale Educational and Livelihood Interventions

Part of project Number/s: **05461**
Country/ies: Bangladesh
Technical Coord.: Sajeda Amin
Period: October 1997 – August 2004
Objective: To explore the impact of education and livelihood interventions that seek to expand opportunities for young women and delay the timing of marriage and the onset of childbearing.

Activity Description:

While Bangladesh has experienced dramatic fertility decline as a result of its successful family planning program, it continues to maintain a regime of very early marriage that has negative implications for rapid population growth. This project studies the impact of two large-scale interventions: a secondary school scholarship scheme and a pilot scheme to impart livelihood skills to adolescent girls.

The first part of the project (1997–2001) uses data from a long-term village study to assess the impact of educational incentive schemes for children and adolescent girls. The second part of the project (2001–2003) applies lessons learned from the village study to an intervention program in three rural districts — Chapainawabganj, Chittagong, and Sherpur. The goal of the intervention is to provide adolescent girls who are recent school graduates with life-skills and livelihood training. Subsequent to the training, some girls may be linked with existing savings and credit facilities. Entrepreneurship development and internship opportunities in the local communities will also be supported. UNICEF is funding the intervention, which is being carried out by BRAC and CMES, two nongovernmental organizations. To create a more supportive environment for adolescent girls, various districtwide sensitization activities are being conducted by the government, including a media campaign and training program for adolescent boys, parents, and members of the local government. The Council is conducting a study of the intervention.

Final Report:

The overall objective of the Bangladesh Adolescent Livelihoods Project, an umbrella project of which this PCP3-funded activity was a part, was to explore how adolescents can be empowered by enhancing their livelihood skills through programmatic interventions. Empowerment was measured in terms of improved control over decisions that are consequential to adolescents' lives, such as schooling and marriage.

The first part of the project (1997–2001) used data from a long-term village study to assess the impact of educational incentive schemes for children and adolescent girls. Data from the early years of the educational program in 1995–96 suggested that incentive schemes introduced in 1994 resulted in rapid increases in school enrolment. Data from the village study in 2000 and from a larger three-district survey in 2001 confirmed that school enrolment increased more for girls than for boys but also indicated that the risk of dropping out of school remained strongly differentiated by gender and class. Boys from poor households dropped out earlier than non-poor boys, and all girls faced similarly high dropout risks because of marriage. Girls continued school until they married, but often did not delay marriage for school. In addition, dowry payments were a menacing concern for parents, and early marriage was encouraged by perceptions that older girls would require higher dowries.

The second part of the project (2001–2003) applied lessons learned from the village study to an intervention program in three rural districts — Chapainawabganj, Chittagong, and Sherpur. A baseline survey conducted in 2001 documented important differences in the three study districts in terms of marriage, dowry demands, reproductive health, and schooling of girls. Between March and June of 2003 a follow-up survey was conducted in 68 of the 90 villages initially interviewed. The follow-up survey tracked girls who had migrated out of their own villages to other areas within the district; 23% of all girls had moved since the baseline. It was found that there were marriage delays which can be attributed to the interventions and that the interventions were more successful among girls in school and from relatively poor households.

The project showed that programs designed to give adolescent girls access to public spaces in which to congregate and interact with their peers; provide life-skills, livelihood skills and reproductive health training; and other support to increase their earning potential, can have far-reaching effects: these programs encouraged increased schooling, increased work and income, and delayed marriage. There are rich qualitative data on how programs such as this can foster and enhance a sense of well-being in participants.

The intervention did not specifically discourage dowry payment. One negative finding of the study was that, in general, those who delayed marriage appear to have paid a higher dowry. Families of girls believe paying dowry is a strategy of choice to ensure the well-being of their daughters, despite the fact that those who marry without dowry are found to be better off in terms of suffering less abuse and enjoying more leisure during the early years of marriage.

This project made an important contribution by documenting who among rural residents is most likely to join and maintain program membership. Although programs are more likely to be used by more educated households within a village, in this study this selectivity was counteracted by the programs appearing to be taken up with the most enthusiasm by those in the poorest and least educated district, Sherpur.

The results from this study have been disseminated widely among development practitioners. Several important policy-making decisions have been influenced by the study. First, a national adolescent survey is underway to identify socially and geographically vulnerable areas and populations. Second, the Population Council is working with implementing agencies to incorporate strategies addressing the issue of dowry into programs aimed at empowering adolescent girls. Third, new programs which will include financial literacy training and micro-credit initiatives are being put together by development NGOs to provide age- and need-appropriate interventions to improve livelihood opportunities in vulnerable adolescent populations.

Implementing Organization(s): Bangladesh Institute for Development Studies (BIDS) (CP00.10A)
Bangladesh Institute for Development Studies (BIDS) (CP00.03A)
Population Council

Collaborating Organization(s): Bangladesh Rural Advancement Committee (BRAC)
Centre for Mass Education and Sciences (CMES)
UNICEF
Women's Directorate, Government of Bangladesh

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Completion Activities and Assessment of Findings: Allahabad Project

Part of project Number/s: **05461**

Country/ies: India

Technical Coord.: Barbara Mensch

Period: January 2003 - December 2004

Objective: To measure the impact of an intervention that adds vocational counseling and training to an adolescent reproductive health project in an urban slum in Allahabad, Uttar Pradesh, India, through analysis of survey and case study data.

Activity Description:

The project investigated the feasibility and impact of adding four components to a preexisting reproductive health program (managed by CARE India) for adolescent girls in Allahabad, India: (1) counseling on savings formation and livelihoods; (2) vocational skills training; (3) assistance in opening savings accounts; and (4) follow-up support. The project used a quasi-experimental pre- and post-test design that compared the intervention group with a control group of adolescents. The project selected peer educators from the slums and trained them in the provision of reproductive health information, communication skills, and group formation techniques. After the peer educators completed the reproductive health education series and had been trained by project staff to provide information about livelihoods and savings opportunities, they conducted group sessions about livelihoods and savings using information, education, and communication materials developed for this purpose. Nineteen short-term vocational training courses were then offered both in the slums where the girls resided and in the city of Allahabad. Concurrently with vocational skills training, counseling and assistance was provided for creating savings accounts at banks or post offices. Evaluation activities included a baseline survey conducted from April through June 2001, a midterm assessment that took place in April 2002, in-depth case studies conducted from February through June 2003, and an endline survey conducted from March through June 2003. USAID funds were used for a subaward to CORT, India to complete the endline survey. Remaining funds covered in-house costs of analyzing the case studies and data from the survey.

Final Report:

Although acceptable to parents and feasible to implement, the livelihoods intervention had a minimal impact on the attitudes and behavior of adolescent girls in the experimental slums. However, significant changes were observed between baseline and endline surveys in the outcomes that most closely reflected the content of the intervention. Girls exposed to the intervention were significantly more likely to have knowledge of safe spaces, be a member of an organized group or society, score higher on a social skills index, be informed about reproductive health, and spend time on leisure activities than were the matched control respondents. No effect was found on gender-role attitudes, mobility, self-esteem, work expectations, or on number of hours visiting friends, performing domestic chores, or engaging in labor-market work.

A number of factors worked against finding significant effects on attitudes and behavior:

· First, only 121 of the 635 girls in the experimental slum for whom we had both baseline and endline data participated in the intervention, reducing the likelihood of finding significant effects.

· Second, fielding a longitudinal survey in urban slum areas was more problematic than anticipated. Finding and successfully interviewing adolescents is a difficult task under the best of circumstances; attempting to do so in densely populated slums is even more demanding of both time and resources.

Despite efforts to ensure complete coverage at endline, we still missed, or could not match, a large number of adolescents who had been interviewed at baseline.

· Third, when we were able to interview the same adolescents in both survey rounds, answers to questions about aspects of the adolescents' lives were often inconsistent or illogical.

· Fourth, in retrospect, the intervention was of too short a duration and of insufficient intensity to produce a sizable effect; the girls were not involved in group meetings or vocational training for a long enough period of time to alter their attitudes or behavior significantly.

· Fifth, many of the vocational courses were not tailored to the girls but were simply "off the shelf." While taking advantage of existing community resources was a deliberate choice to encourage replication of the intervention, courses designed specifically for the target population might have had a greater impact.

· Sixth, the intervention involved only minimal contact with the girls' parents. Since to a large extent girls are not in control of their futures, parents must be fully engaged in discussions of their daughters' lives.

· Finally, many of the outcome variables used to evaluate the effectiveness of the intervention were not appropriate. They were selected because of an assumption that the intervention would have a broad impact on the social context of young women's lives; instead, we found changes only for those variables directly affected by the intervention. Future evaluations should, from the outset, identify indicators that better reflect the subtleties of the changes that might be expected to result from the intervention.

Although the results were somewhat disappointing, there were significant changes found in those outcomes that most closely reflected the content of the interventions. An increased knowledge of safe spaces for girls and self-identification as a group member were direct effects of participation in the groups that met at the homes of the peer educators. Likewise, the increased social skills were a by-product of informal interaction within the peer groups. The most encouraging outcome was that intervention participants showed a significant increase in reproductive health knowledge over the control respondents who also had attended the reproductive health classes, but without the added livelihoods component. Although some of this improvement in knowledge may be related to better attendance at the reproductive health classes in the experimental areas—enrollment in the vocational training classes was conditional on good attendance during the reproductive health component—some unmeasured aspect of the livelihoods component may have encouraged the retention of reproductive health information.

In this highly traditional slum community, a livelihoods program was not only acceptable to parents, but also feasible to implement. Although a short-term program cannot alter the structure of opportunities available, it can increase awareness, social skills, knowledge of safe spaces for meeting, and group identification. However, in order to reduce deeply-entrenched gender disparities and enhance girls' ability to have a greater voice in decision making about their own lives, future interventions should involve many more contact hours than did this experimental project. Greater effort should be devoted to developing group cohesion and improving communication, negotiation, and decision making skills. Finally, in future interventions, substantially greater resources must be provided for data collection so that the effects of the interventions can be thoroughly evaluated.

Implementing Organization(s): Centre for Operations Research and Training (CORT), India (CP03.02A)
Population Council

Collaborating Organization(s): CARE India

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

The Reporting of Sensitive Behavior Among Adolescents: A Methodological Experiment in Kenya

Part of project Number/s: **05462**

Country/ies: Kenya

Technical Coord.: Barbara Mensch

Period: June 1999 – June 2003

Objective: To assess whether audio computer-assisted self-interviewing (audio-CASI) is feasible for use in a developing country and whether it produces more reliable data on sexual activity and related behaviors than traditional survey methods.

Activity Description:

If reporting of sexual activity and other sensitive reproductive behaviors is unreliable, social science analyses that document the behaviors are undermined, and program evaluations that determine the effectiveness of interventions designed to improve adolescent reproductive health are compromised. This study assessed whether audio-CASI is feasible for use in a developing country and whether it produces more accurate reporting of sexual activity and related behaviors than traditional survey methods. With audio-CASI, a respondent hears both the question and the response categories through headphones. The respondent answers each question by pressing a number on a keypad or computer keyboard. Increased privacy is one advantage of audio-CASI over face-to-face interviews; questions and responses are heard by the respondent only. Moreover, unlike self-administered interviewing, which requires that the respondent be literate and competent to fill out a questionnaire, audio-CASI can be carried out even when the respondent cannot read questions on a computer screen. The study was carried out in Nyeri District, where data collection was conducted from April to October 2000 and again from August to October 2001, and in Kisumu District where data collection began in April 2002 and was completed in July 2002.

Final Report:

Three papers were written on audio-CASI. The first investigates whether audio-CASI produces more valid reporting of sexual activity and related behaviors than either face-to-face interviews or self-administered interviews. Results indicate substantial and significant differences in reported rates of premarital sex across interview modes, although not always in the expected direction. The assumption that girls underreport sexual activity in face-to-face interviews by comparison with audio-CASI was not confirmed by the Nyeri data. On the other hand, the results from Kisumu are considerably more promising. For the most part, audio-CASI does generate significantly higher levels of reporting of sensitive behavior among girls, particularly among girls enrolled in school.

The second paper describes the experience of carrying out a household-based study using computers and explores the technical challenges faced by the data collection teams. The audio-CASI technology performed quite well during approximately ten months of interviewing, despite the rigorous conditions of working in a largely rural, sub-Saharan African setting. Further, respondents in the audio-CASI mode were no more likely than other respondents to stop and ask for assistance during the interview. However, the substantial number of invalid entries made by respondents in the audio-CASI mode suggests that respondents did not completely master the use of the keypad during the interview. Moreover, the overall success of computerized interviewing was found to be dependent on the local context in which interviewing took place. In Kisumu, where community members were more favorably disposed to the survey, computerized interviewing was no more difficult to implement than other modes. The experience in Nyeri, on the other hand, suggests that where segments of the community have doubts about project activities, the use of computers can exacerbate the suspicions of parents and adolescents.

The third paper analyzes 709 unmarried adolescent females ages 15–21 in Kisumu who were assigned either to the interviewer-administered group or the audio-CASI group. In Kisumu the questionnaire was altered so that all the sexual behavior questions were asked of every respondent, even those who answered negatively to the initial question about ever having had sex. When respondents in face-to-face interviews are asked additional questions about sex, including types of sexual partners and experiences with coerced sex, no one who said she hadn't had sex when asked initially gave answers to the subsequent questions that indicated she had had sex. On the other hand, audio-CASI respondents who answered no to the ever-had-sex question gave responses to the subsequent questions indicating they had had sex. Indeed, while only 43 percent of audio-CASI respondents answered yes to the question of ever having sex, when sex with specific partners is used to measure the prevalence of premarital sex, the percentage increases to 61. When coerced sex is included, the percentage increases to 68. The percentage of respondents reporting they have had sex remains at 48 in the interviewer-administered group even when asked the subsequent questions. Clearly, the level of consistency in the interviewer mode is suspect. While interviewers were trained not to enforce consistency or to point out contradictory answers to respondents, the possibility remains that interviewers are not inclined to continue to ask all sexual activity questions, perhaps filling in the questionnaire without asking further questions if the respondent was adamant about not having had sex early in the survey. Such a practice would produce an underestimate of premarital sex if, as indicated by the audio-CASI results, respondents are likely to answer no to ever having sex, yet respond positively to other sexual activity questions.

Researchers believe it is premature to draw firm conclusions about the efficacy of computer interviewing on the basis of these experiences in Kenya. There is a long history of scholarly work in the United States and Europe on the interviewing process and response effects in surveys. Clearly, research in this area also needs to be conducted in developing countries.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

The Reporting of Sexual Activity in Malawi

Part of project Number/s: **05462**
Country/ies: Malawi
Technical Coord.: Barbara Mensch
Period: July 2003 – December 2004
Objective: To assess whether audio computer-assisted self-interviewing (ACASI) improves the reporting of sexual behavior among a sample of unmarried females aged 15–21 in Balaka, Malawi

Activity Description:

This activity was part of a larger research project entitled "AIDS/HIV Risk, Marriage and Sexual Relations in Malawi," conducted by the University of Pennsylvania Population Studies Center (Hans-Peter Kohler, principal investigator) with funding from the U.S. National Institutes of Health. The goal of the University of Pennsylvania project was to understand how individuals in high-HIV-risk environments cope with AIDS, manage risk, and adapt their sexual behavior. The project included four rounds of longitudinal data collection from women and their husbands between 1998 and 2005. The Population Council provided technical assistance by assessing whether ACASI improves reporting of premarital sexual behavior among young girls. Council researchers implemented a randomized experiment of ACASI relative to face-to-face interviewing in a sample of females aged 15-21 in Balaka District, one of the three districts where the longitudinal survey was being conducted. If ACASI is found to improve reporting of premarital sexual behavior, it will serve to inform staff at the University of Pennsylvania of potential reporting biases in their main sample of women and men.

Final Report:

Between July 2003 and April 2004, we designed the study, which involved calculating the sample size, developing the questionnaire, recording the audio in local languages, and training the interviewers. From May through July 2004 a sample of 500 unmarried female adolescents aged 15-21 were interviewed in rural areas of Balaka district, Malawi. Respondents were randomized to either a face-to-face or ACASI interview and were asked a series of questions about their sexual behavior, partnership history, and attitudes toward HIV/AIDS. The adolescent surveys were completed at the household level in enumeration areas geographically close to the University of Pennsylvania's longitudinal study sites. Oral swabs were collected and tested for HIV, and respondents provided urine samples for testing of gonorrhea and chlamydia. The collection of biomarkers will allow for the investigation of the association between risky sexual behavior and STI/HIV status by interview mode. If, as is hypothesized, respondents are less likely to admit to risky sexual behavior in face-to-face interviewer-administered surveys than in ACASI, the association between STI status and self-reported behaviors should be lower for face-to-face interviews than that observed with ACASI, other things being equal.

Although the data have not been completely analyzed, preliminary evidence, shown in the table below, indicates that the mode of interview has an effect on the reporting of sexual behavior. However, the results are not always consistent with expectations. For instance, although we expected ACASI to promote higher reporting for all questions regarding sexual behavior, it did not do so for the "ever had sex" and "ever had sex with a boyfriend" questions, and reporting for "ever had sex with a fiancé" was only marginally higher in ACASI interviews than in the face-to-face interviews.

Table. Predicted Percentages of Sexual Behaviors by Interview Mode

(Note: For each behavior, the box indicates which mode produced higher reporting)

	Interview Mode	
	Face-to -Face	**Audio CASI**
Girls		
Ever had sex	47.2	34.1
Ever had sex with a boyfriend	30.1	20.4
Ever had sex with a fiancé	27.1	28.6
Ever had sex with an acquaintance or friend	7.0	17.5
Ever had sex with a family member	1.3	6.8
Ever had sex with a teacher	1.4	4.4
Ever had sex with an employer	0.0	1.8
Ever had sex with a stranger	2.6	3.4

This preliminary evidence shows that the use of ACASI results in higher reporting for the questions that are clearly more socially stigmatizing, specifically, for ever having had sex with an acquaintance or friend, family member, teacher, employer, or stranger.

These results are very similar to those found in a comparable study of adolescent sexual behavior in Kenya (Mensch, Hewett and Erulkar 2001; Hewett, Mensch and Erulkar 2003). Although the comparability of results between two countries provides a sense of reliability regarding the findings, it does not explain the inconsistency between expected and actual response patterns in the reporting of sexual activity by interview mode, as discussed above.

More research, including additional in-depth analyses and evaluation of these Malawi findings, is required before a conclusion can be made regarding the most appropriate interview methodology for sensitive sexual behaviors.

Implementing Organization(s): Population Council

Collaborating Organization(s): University of Pennsylvania

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Transition to Adulthood in the Context of AIDS in South Africa

Part of project Number/s: **05462**

Country/ies: South Africa

Technical Coord.: Kelly Hallman

Period: February 1999 – October 2004

Objective: To document patterns and trends for key events during adolescents' transitions to adulthood, and to evaluate the impact of life-skills programs on adolescent sexual behavior in South Africa.

Activity Description:

In 1999, HIV prevalence among South African antenatal clinic attendees aged 19 and under and 20-24 exceeded 16 and 25 percent, respectively. Adolescent childbearing levels were also high: the 1996 census showed that 30 percent of females aged 20-24 had given birth before age 20. A study of adolescents in KwaZulu-Natal Province (the province hardest hit by the AIDS epidemic) seeks to address multiple knowledge gaps about adolescent risky behavior. The main goals of the study are: (1) to document patterns, trends, and relationships among key events during the transition to adulthood — including sexual initiation, school-leaving, employment, and childbearing; and (2) to evaluate the impact of school-based life-skills instruction on adolescent sexual behaviors. The study is longitudinal and multilevel.

Population Council Policy Research Division (PRD) staff collaborated with researchers from Horizons, MEASURE Evaluation, FOCUS, and the University of Natal-Durban on the design and implementation of the study and data analysis. Funding from the PCP3 supported PRD staff and consultants. Horizons and MEASURE Evaluation supported field costs via funds from the USAID Mission in South Africa.

Final Report:

A representative sample of 3,000 adolescents aged 14-22 years in Durban Metro and in Mtunzini magisterial district in KwaZulu-Natal was interviewed in September 1999. The same year, principals of secondary schools in the study area were interviewed about life-skills instruction in their schools. In May 2000, community data were collected to assess the presence and quality of community infrastructure, and street intercept interviews were conducted with local residents to measure local attitudes about safety and youth HIV risk. In 2001, a second round of interviews was conducted with school principals and with all 14-24 year-olds residing in study communities, and, in addition, all adolescents from the 1999 survey no longer residing in the study communities were tracked down and interviewed.

A number of analyses were undertaken with these data, with the major findings including:
(1) While most young people had attained at least primary education by age 20, there were large differences by wealth status and race in educational attainment. Males and females residing in low wealth households were more likely to have experienced delays in their schooling. The negative effect of low wealth on educational attainment was larger for females than males.
(2) Females advanced more quickly than males through primary school, but many young women had pregnancy-related interruptions during secondary school. Higher rates of pregnancy were observed among low wealth young women. Young women between 20-24 years of age who had a teen pregnancy were half as likely to have completed secondary school than those who did not.
(3) For females, experiencing nonconsensual sex was associated with lower rates of school enrollment and education attainment.

(4) For females and males, low wealth reduced age at sexual debut. For females, low wealth reduced the chances of using a condom at last sex and discussing safe sex practices with the most recent sexual partner; and increased odds of exchanging sex for money, goods, or favors, of experiencing coerced sex, and of having multiple sexual partners in the last 12 months.
(5) Controlling for wealth and other factors, orphanhood was associated with certain unsafe sexual behaviors. Female and male paternal orphans debuted earlier sexually, and male paternal orphans had lower odds of practicing secondary abstinence. Male maternal orphans had lower chances of discussing safe sex practices with their most recent sexual partner.
(6) Social isolation was associated with higher rates of nonconsensual sex for females.
(7) Girls in communities with high levels of school enrollment were less likely to have had sex in the 12 months before the survey. For both sexes, high wages earned by the youth decreased their likelihood of having sex in the 12 months before the survey, and, if they did have sex, increased their likelihood of using a condom.
(8) Evaluation of the school-based life-skills program indicated short-term effects in certain areas of sexual and reproductive health–related knowledge and behaviors. These included increases in perceived confidence in being able to obtain condoms when needed, in being able to use them effectively, and increases in condom use at first and last sex.

Population Council staff collaborated with the University of Natal-Durban to take inventory of programs in the Durban Metro area that focused on at least one of the following areas: youth, gender, HIV/AIDS, safe spaces, and economic empowerment. We found that most programs emphasized only one of these dimensions. Discussions with program managers during the inventory, however, indicated strong interest in a more interdisciplinary approach. In response to our research findings and the program inventory, the Population Council initiated a collaboration with local partners in late 2004 to develop, implement, and evaluate a flexible and integrated community-based program to increase young people's social networks and support, financial literacy skills, and HIV/AIDS knowledge. The pilot project is in progress.

Study results have been presented at several international conferences: the Population Association of America Annual Meeting (2003, 2004, and 2005), the XV International AIDS Conference in Bangkok (2004), and the 2nd South African AIDS Conference (2005). The results have also been presented at UNICEF Headquarters in New York and Pretoria (2003; 2004) and at the United Nations 49th Session of the Commission on the Status of Women (2005). Study results have been disseminated via Population Council Policy Research Division Working Papers, Population Council Horizons reports, and articles in peer-reviewed journals, including the *Journal of Adolescent Health*, *AIDS Behavior* , the *African Journal of AIDS Research* , *Reproductive Health Matters*, and *Studies in Family Planning.*

Implementing Organization(s): Population Council
Collaborating Organization(s): Pathfinder/FOCUS
Population Council/Horizons
Tulane University/MEASURE Evaluation
University of Natal-Durban

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Transitions in Reproductive Behavior in the Developing World

Program Summary

Principal Findings

Over the past three decades, a revolution in reproductive behavior has swept through most of the developing world. Contraceptive use, once rare, is now widespread. The average number of births per woman has fallen by half—from six or more to nearly three. This program carried out four studies which shed light on several key issues related to the prospects for future trends in fertility and contraceptive use.

1) The Future Demand for Contraception

Around 1960 only a tiny fraction of couples practiced contraception, and knowledge of contraceptive methods was very limited. In contrast, today more than 60 percent of couples in the developing world are current users of contraception. While past trends in contraceptive behavior are fairly well established, there is considerable uncertainty about what lies ahead. Because contraceptive prevalence among married women of reproductive age in the developing world is approaching levels observed in many developed countries it might be tempting to conclude that contraceptive demand is about to level off.

This study found that instead of leveling off in the near future, the demand for contraception can be expected to continue to rise rapidly for the next several decades, for two main reasons:

(a) *Population continues to grow.* According to the 1998 revision of the UN population projection, the population size of the developing world will grow from 4.5 to 7.8 billion between 1995 and 2050. The proportion of the population in the reproductive age groups is expected to remain fairly steady. As a result, the number of women of reproductive age will grow at about the same rate as the population as a whole.

(b) *Fertility continues to decline.* The total fertility rate in the developing world has dropped to about three births per woman, but it remains 50 percent above the replacement level. Most existing population projections expect the fertility transition to continue until the replacement level is reached. To bring about this fertility decline, contraceptive prevalence will have to rise substantially. It is reasonable to assume that prevalence in the developing world will reach levels of about 75 percent as now observed in countries at replacement.

As a result of these trends, the number of users of contraception in the developing world is expected to rise from 549 million to 816 million over the next 25 years, according to the most recent UN projection. An examination of existing projection methodologies found results for prevalence to be reasonable, but method specific results are potentially problematic. A new method for projecting contraceptive use by method was developed and applied.

2) Analysis of the "Birth Dearth" Hypothesis

Fertility has dropped below the replacement level in virtually every population that has moved through the demographic transition. This trend was not widely anticipated by demographers and until recently little attention has been given to understanding the causes and consequences of low fertility in post-transitional resulting in large population declines and rapid aging.

societies. Proponents of the "birth dearth" hypothesis believe that fertility will remain at this low level, resulting in large population declines and rapid aging.

This study examined an alternative explanation for very low fertility, namely that women are postponing births to later ages, which temporarily depresses fertility owing to so-called tempo distortions. According to this view current low fertility is unlikely to decline much further and may even rise in the future in a number of post-transitional countries. The most widely used measure of fertility—the total fertility rate—was found to contain substantial tempo distortions, thus giving misleading estimates of actual levels and trends in childbearing in many post-transitional countries. Once the rise in the mean age of fertility ends—as it eventually must—the corresponding fertility-depressing effect stops, thus putting upward pressure on period fertility. Such an upward trend has already been observed in a few countries. Further evidence supporting this conclusion is found in the fact that the total fertility rate in most of these countries is well below the desired family size of about two children. The implication of these findings is that the "birth dearth" is exaggerated. Very low post-transitional fertility is unlikely to be maintained and will probably rise closer to the replacement level in the future. Even though population sizes will decline modestly in a number of countries with below replacement fertility, there is little prospect of rapid population decline throughout the world.

3) Variations in Contraceptive Prevalence at the End of the Fertility Transition

The widespread fertility declines that have occurred throughout the developing world over the past few decades have invariably been accompanied by large increases in contraceptive use. This study examined the causes of unexpected variation in contraceptive prevalence in countries that have reached the latest stage of the fertility transition (i.e. with a total fertility rate less than 3 births per woman). In these countries contraceptive prevalence among all women varies from a low of 40 percent in Colombia (1990) to 72 percent in Vietnam (1997) and among married women prevalence varies from 48 percent in India (1998/99) to 78 percent in Vietnam (2001) a range of 32 and 30 percentage points respectively. Several factors were found to be responsible for this variation:

(a) Expected variation. Some of the variation in prevalence in late transitional countries is due to small but real differences in fertility at the end of the transition.

(b) Measurement errors. Survey estimates of fertility and contraceptive prevalence contain small sampling and non-sampling errors

(c) Effects of other proximate variables. Fertility is directly determined by a set of behavioral and biological variables called the proximate determinants. Contraceptive use is the most important of these, but there are a number of others including the incidence of induced abortion, proportions married, post-partum infecundability, contraceptive effectiveness, and frequency of intercourse. Any true variation in prevalence around the expected level is caused by variation in these other proximate variables.

4) Stalling Fertility Transitions

Many developing countries experienced rapid fertility declines during the 1970s and 1980s. Conventional theory suggests that these fertility transitions will continue until fertility reaches the replacement level of 2.1 births per woman. However, contrary to expectations, fertility in the 1990s has declined less rapidly

than projected earlier in a number of countries. In fact, in Bangladesh, Colombia, the Dominican Republic, Ghana, Egypt, Kenya and Peru fertility has stalled or nearly stalled at around three births per woman. This surprising development has led the UN to revise upward its fertility assumptions for a substantial number of countries in its most recent projections (2000) and, as a result, the population projection for the world population in 2050 has been revised upward by 410 million (from 8.91 to 9.32 billion).

This study identified the main causes for this stalling, which operate at different levels of analysis ranging from proximate to more distant socioeconomic determinants:

(a) Proximate determinants. Stalling fertility is typically associated with a leveling off of contraceptive prevalence. This is the case, although unmet need for contraceptives to space and limit births remains substantial.

(b) Fertility preferences. Stalling in overall fertility is associated with stalling of fertility preferences. Stalling occurs when either wanted or unwanted fertility levels off above the expected levels at the end of the transition, and stalls in both wanted and unwanted fertility often are observed.

(c) Access to family planning . In all stalling countries unmet need for contraception remains substantial. No evidence of a rise in unmet need or unwanted fertility was found which suggest that there may not have been a large deterioration of family planning services.

(d) Socioeconomic factors. The persistence of large fertility differentials together with low levels of schooling among married women is a key cause of this stalling in several countries.

Publications

"The causes of stalling fertility transitions in the developing world" *Studies in Family Planning* 37(1) (forthcoming)

"Completing the fertility transition in the developing world: The role of educational differences and fertility preferences," *Population Studies*, Vol. 57(3): 321-336, 2003.

"The end of the fertility transition in the developing world," *Completing the Fertility Transition.* Department of Economic and Social Affairs, Population Division, ESA/P/WP.172/Rev.1. New York: United Nations, pp. 288-307, 2002.

"The end of the fertility transition in the developed world," *Population and Development Review* 28(3): 419-433, 2002.

"Future trends in contraceptive prevalence and method mix in the developing world," *Studies in Family Planning* 33(1): 24-36, 2002, (with Elof Johannson).

The Future Demand for Contraception

Part of project Number/s: 04800

Country/ies: Interregional

Technical Coord.: John Bongaarts

Period: August 1999 - August 2000

Objective: To review the methodologies used in projections of future trends in the demand for contraception, to assess the validity of the assumptions underlying these projections, and to propose methodological improvements.

Final Report:

Projections of future levels of contraceptive use have been made recently by the United Nations and The Futures Group. The UN projects contraceptive prevalence and numbers of users for different world regions from 1993 to 2025. The Futures Group provides similar results for individual developing countries to 2015 and also projects the number of users of different methods.

The practice of contraception in the developing world has changed dramatically over the past three decades. Around 1960 only a tiny fraction of couples practiced contraception, and knowledge of contraceptive methods was very limited. In contrast, today contraceptive knowledge is widespread; more than half of couples in the developing world are current users of contraception. An even larger proportion has ever used the method. The large majority of these users rely on modern methods of contraception, including male and female sterilization, IUD, and the pill. This revolution in contraceptive behavior has been driven by a desire to reduce family size as well as by the diffusion of information about and access to contraceptive methods, aided by a rapid expansion of family planning programs in many developing countries. These trends have helped women implement their preferences for smaller families and avoid unwanted pregnancies.

While past trends in contraceptive behavior are fairly well established, there is considerable uncertainty about what lies ahead. Because contraceptive prevalence among married women of reproductive age in the developing world is approaching levels observed in many developed countries it might be tempting to conclude that contraceptive demand is about to level off. If that were indeed the case, investments in family planning and reproductive health programs would likely receive lower priority in the future.

This study found that instead of leveling off in the near future, the demand for contraception can be expected to continue to rise rapidly for the next several decades, for two main reasons:

1) *Population continues to grow.* According to the 1998 revision of the UN population projection, the population size of the developing world will grow from 4.5 to 7.8 billion between 1995 and 2050. The proportion of the population in the reproductive age groups is expected to remain fairly steady. As a result, the number of women of reproductive age will grow at about the same rate as the population as a whole.

2) *Fertility continues to decline.* The total fertility rate in the developing world has dropped to about three births per woman, but it remains 50 percent above the replacement level. Most existing population projections expect the fertility transition to continue until the replacement level is reached. To bring about this fertility decline, contraceptive prevalence will have to rise substantially. It is reasonable to assume that prevalence in the developing world will reach levels of about 75 percent as now observed in countries at replacement.

As a result of these trends, the number of users of contraception in the developing world is expected to rise from 549 to 816 million over the next 25 years, according to the most recent UN projection. An examination of the projection methodology found it to be reasonable. The number of users of contraception will increase much more rapidly in Africa than in Asia or Latin America, because growth in both factors affecting the demand for contraception will be higher in Africa than elsewhere.

Projecting the future distribution of specific contraceptive methods is more difficult. Method choice is affected by trends in several factors, including access to different methods, user characteristics, and technology. In addition, the health effects of contraceptives will become a more important consideration to women and men in the future, because contraceptives will be used during a large proportion of the reproductive years.

The procedures employed by The Futures Group to project the method mix were found to be less than optimally designed, and a new methodology was therefore developed by this investigator. The general approach used in this methodology is one of slow and incomplete convergence toward a more balanced method mix in each country, with uniform reductions in the role of traditional methods. The new alternative projections to 2015 are quite different from those made by The Futures Group. For example, for the developing world as a whole the proportions of contraceptive users relying on female sterilization are projected to be higher in 2015 (37 percent rather than 26 percent), and proportions using traditional methods will be lower (7 percent instead of 14 percent). Trends for individual countries are also quite different. For example, a more modest decline in female sterilization is forecast for India (from 67 percent to 53 percent rather than to 32 percent), and increases are expected in Pakistan (from 28 percent to 32 percent) and in Bangladesh (from 15 percent to 25 percent) rather than declines in both countries to 7 percent in the Futures Group projection. Overall this study expects the mix of contraceptives to change slowly over the coming years. No dramatic new product currently in development will radically alter the current pattern. However, a gradual increase in availability of a wider range of methods is likely as the quality of services improves, as markets for contraceptives become more open, and as levels of contraceptive knowledge and education rise. This should result in a greater variety of contraceptives in use and a more balanced distribution among different modern methods. These trends will likely favor new hormonal contraceptives, especially if their cost can be reduced, and diminish the current heavy reliance on female sterilization.

The findings from this study have been summarized in a paper coauthored by John Bongaarts and Elof Johansson, “Future trends in contraception in the developing world: Prevalence and method mix,” which was published recently as a working paper of the Council’s Policy Research Division and has been accepted for publication in *Studies in Family Planning.*

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Analysis of the "Birth Dearth" Hypothesis

Part of project Number/s: 04800

Country/ies: Interregional

Technical Coord.: John Bongaarts

Period: September 2000 – August 2001

Objective: To assess the validity of the "birth dearth" hypothesis, which claims that ongoing fertility declines will soon lead to population declines not only in the industrialized world but also in many developing countries.

Final Report:

Fertility has dropped below the replacement level in virtually every population that has moved through the demographic transition. This trend was not widely anticipated by demographers and until recently little attention has been given to understanding the causes and consequences of low fertility in post-transitional societies. Proponents of the "birth dearth" hypothesis believe that fertility will remain at this low level, resulting in large population declines and rapid aging. An alternative explanation for this low fertility proposed by Bongaarts is that women are postponing births to later ages, which temporarily depresses fertility owing to so-called tempo distortions. According to this view current low fertility is unlikely to decline much further and may even rise in the future in a number of post-transitional countries.

To test this alternative hypothesis the project has (1) collected age- and order-specific birth rates and cohort fertility rates from developed countries; (2) estimated the tempo distortions with methodology proposed by Bongaarts and Feeney; and (3) compared observed total fertility rates with the tempo-free rates as well as with cohort total fertility and fertility preferences to determine the prospective trends in fertility, if and when the temporary tempo distortions are removed.

The analysis documented that the most widely used measure of fertility—the total fertility rate—contains substantial tempo distortions, thus giving misleading estimates of actual levels and trends in childbearing in many post-transitional countries. Once the rise in the mean age of fertility ends—as it eventually must—the corresponding fertility-depressing effect stops, thus putting upward pressure on period fertility. Such an upward trend has already been observed in a few countries. Further evidence supporting this conclusion is found in the fact that the total fertility rate in most of these countries is well below the desired family size of about two children. The implication is that the "birth dearth" is exaggerated. Very low post-transitional fertility is unlikely to be maintained and will probably rise closer to the replacement level in the future. Even though population sizes will decline modestly in a number of developed countries, there is little prospect of rapid population decline throughout the developed world.

The findings from this study have been summarized in a paper—"The end of the fertility transition in the developed world" coauthored by John Bongaarts—that will be published as a Policy Research Division Working Paper and in the March 2002 issue of *Population and Development Review*.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Analysis of the Causes of Stalling Fertility Transitions

Part of project Number/s: 04800

Country/ies: Interregional

Technical Coord.: John Bongaarts

Period: July 2001 – June 2003

Objective: To assess the causes of stalling fertility declines in the 1990s in selected developing countries.

Activity Description:

Many developing countries experienced rapid fertility declines during the 1970s and 1980s. Conventional theory suggests that these fertility transitions will continue until fertility reaches the replacement level of 2.1 births per woman. This assumption has been incorporated into past population projections made by the United Nations (UN), the World Bank, and the International Institute for Applied Systems Analysis. However, contrary to expectations, fertility in the 1990s has declined less rapidly than projected earlier in a number of countries. In fact, in Bangladesh, Colombia, the Dominican Republic, Egypt, and Peru fertility has stalled or nearly stalled at around three births per woman. This surprising development has led the UN to revise upward its fertility assumptions for a substantial number of countries in its most recent projections (2000) and, as a result, the population projection for the world population in 2050 has been revised upward by 410 million (from 8.91 to 9.32 billion). This study documents the extent of deceleration in fertility declines and examines several possible explanations for these recent unexpected fertility trends.

Final Report:

During the 1990s a number of mid- and late-transitional countries experienced a reduction in the pace of fertility decline, and in some countries fertility has virtually stalled (e.g., in Bangladesh, the Dominican Republic, and Egypt, and probably in India).

This study identified the causes of this stalling, which operate at different levels of analysis ranging from proximate to more distant socioeconomic determinants:

(1) *Proximate determinants*. Stalling fertility is typically associated with a levelling off of contraceptive prevalence. This is the case, although unmet need for contraceptives to space and limit births remains substantial.

(2) *Fertility preferences*. Countries that complete their transitions to replacement fertility always experience a steady decline in wanted fertility to below the replacement level while unwanted fertility typically first rises and then falls. The rise in unwanted fertility in the early transitional stage is attributable to a rise in the exposure to unwanted pregnancy as wanted fertility declines. In the later stages of the transition unwanted childbearing declines as women exert more control over their fertility. Stalling in overall fertility occurs when either wanted or unwanted fertility levels off above these expected levels at the end of the transition, and stalls in both wanted and unwanted fertility often are observed.

(3) *Socioeconomic factors*. The fertility declines now under way in many developing countries are almost always associated with substantial fertility differences among socioeconomic subgroups. An inverse correlation between level of education and fertility is found in most developed and developing countries. Low average levels of schooling are an obstacle to further fertility declines. For example, the proportion of

married women with no schooling is 42 percent in Egypt and 45 percent in Bangladesh and the total fertility rate (TFR) among these women is above 4. Fertility dropped rapidly in these two countries between the 1960s and early 1990s, but appears to have stalled during the 1990s at a TFR slightly above 3. The persistence of fertility differentials together with low levels of schooling among married women is a key cause of this stalling.

A lack of sufficiently detailed data prevented a precise quantification of the effect of changes in the timing of childbearing in stalling, but there is little doubt that these changes can play a key role.

These findings provide valuable insights for policymakers interested in accelerating fertility transitions. If unwanted fertility is particularly high, family planning services should be improved so that couples have access to the means to implement their preferences. If unwanted fertility is especially high among the uneducated (e.g., as it is in a number of Latin American countries) then the focus of efforts to improve services should be on this group. In countries where wanted fertility is high, other approaches will need to be considered. Although disagreement remains about the socioeconomic causes of fertility decline, investments in human capital such as education and lower mortality are considered particularly important. Regardless of whether declines in wanted or unwanted fertility are sought, they will be facilitated by improvements in levels of schooling.

Results of the study appear in two publications: “The end of the fertility transition in the developing world” (in *Completing the Fertility Transition*, Population Division, ESA/P/WP.172/Rev.1. New York: United Nations, pp. 288–307, 2002) and “Completing the fertility transition in the developing world: The role of educational differences and fertility preferences” (in press).

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Variations in Contraceptive Prevalence at the End of the Fertility Transition

Part of project Number/s: **04800**

Country/ies: Interregional

Technical Coord.: John Bongaarts

Period: July 2003 – June 2004

Objective: To analyze contraceptive prevalence levels and trends at the end of the fertility transition.

Activity Description:

The widespread fertility declines that have occurred throughout the developing world over the past few decades have invariably been accompanied by large increases in contraceptive use. Past studies of the proximate determinants of fertility confirm that high levels of contraceptive use are the main direct cause of low fertility. However, in contemporary developing countries the levels of contraceptive use associated with a given level of fertility vary widely. For example, in countries with total fertility rates between 2 and 3 births per woman where Demographic and Health Surveys (DHS) have taken place, contraceptive prevalence ranges from a low of 39.9 percent in Colombia (1990) to 71.7 percent in Vietnam (1997). The objective of this study is to determine the causes of variation in contraceptive use associated with low fertility in countries nearing the end of their transitions. The study will analyze information from DHS on levels, trends, and socioeconomic differentials in fertility, contraceptive use, and other proximate determinants.

Final Report:

This study examined the causes of unexpected variation in contraceptive prevalence in countries that have reached the latest stage of the fertility transition (i.e. with a total fertility rate less than 3 births per woman). In these countries contraceptive prevalence among all women varies from a low of 40 percent in Colombia (1990) to 72 percent in Vietnam (1997) and among married women prevalence varies from 48 in India (1998/99) to 78 in Vietnam (2001) a range of 32 and 30 percentage points respectively. Several possible explanations were explored using data from DHS countries (ex-Soviet countries are excluded):

1) *Expected vs. unexpected variation*. Some of the variation in prevalence in late transitional countries is due to small but real differences in fertility. To remove this expected variation from the analysis, contraceptive prevalence variation is re-measured as deviation from the regression line relating prevalence to TFR. Differences between observed and expected prevalence ranged from +5 % in Columbia (2000) to –20% in India (1998/99). After taking into account this fertility effect there is still a great deal of unexplained variance in contraceptive prevalence.

2) *Measurement errors*. Estimates of fertility and contraceptive prevalence from DHS surveys contain inaccuracies due to sampling, design, data collection and reporting errors. In late transitional countries sampling errors are modest with typical confidence intervals of +/– 0.2 births per woman in the TFR and of +/– 2% in the prevalence rate. In well implemented surveys, non-sampling errors should also be small, but their magnitude is not easily measured. However, non-trivial deviations of prevalence from the regression line of +/– 5% should not be unusual, because errors in the TFR and prevalence can reinforce one another. Together these various errors explain a significant part of the observed variation.

3) *Effects of other proximate variables*. Fertility is directly determined by a set of behavioral and biological variables called the proximate determinants. Contraceptive use is the most important of these, but there are a number of others including the incidence of induced abortion, proportions married, post-partum infecundability, contraceptive effectiveness, and frequency of intercourse. Any true variation in prevalence around the expected level is caused by variation in these other proximate variables. The largest deviations were negative (i.e. observed prevalence less than expected from the regression). An analysis with the Bongaarts proximate determinants model identifies the following factors as being responsible for these negative deviations:

- South Africa (–10%): Late age at marriage
- Turkey (–8%): High abortion rate
- India (–20%): High prevalence of sterilization, long post-partum amenorrhea, downward bias in TFR, use of abortion.
- Indonesia (–10%): Effective method mix, long duration of post-partum amenorrhea.

Taken together these three explanations provide a comprehensive assessment of why prevalence varies widely among late transitional countries.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Urban Studies

Program Summary

The Urban Studies Program was comprised of two research projects focusing on urban poverty and health in developing countries which received funding under the Population Council Program III (PCP3) from USAID's Making Cities Work (MCW) Partnership Fund.

The Nairobi Urban Health and Poverty Project: Clarifying Operational Details of the Experiment

In 2000, USAID's cognizant technical officer for the PCP3 encouraged the Council to apply to the MCW Partnership Fund to match Office of Population "special initiative" funds in support of the Nairobi Urban Health and Poverty Project (NUHPP). The NUHPP is a project of the Council-affiliated African Population and Health Research Centre (APHRC) intended to address the need for systematic research and experimental interventions focusing on problems of the urban poor.

The application was successful, and consequently the PCP3 supported a needs assessment in 2002 in the four slum settlements where the NUHPP project was slated. Results from the assessment showed that while slum residents are generally aware of illnesses and treatment, their health-seeking behavior is largely limited by a lack of financial resources. Slum residents are faced with poor access to safe and adequate drinking water and lack of sanitation and disposal facilities. A lack of food in quantity and quality leads to problems with malnutrition. Slum communities rely on expensive profit-driven health facilities that operate informally and are staffed with poorly-trained professionals. With regard to livelihoods, the majority rely on small business and casual jobs for income-generating opportunities. Access to credit is also a major concern.

The assessment helped the NUHPP identify a "minimum package" of health and livelihood interventions for the experiment that followed. These included:

• *Induce behavior change* in home-based care for sick children, and child feeding practices.
• *Strengthen the capacity of public health facilities* to manage childhood illnesses.
• *Improve water and sanitation systems* using simple technologies.
• *Improve household livelihoods* by enrolling slum residents into savings schemes, credit facilities, targeted skills training programs, and a tools bank to enable those with valuable artisan skills to generate income; and by instituting a community health insurance scheme.

In 2004, the APHRC was awarded funding by the European Commission and the Government of Finland to pilot test the strategy in Kenya and to conduct exploratory research in Ghana and Malawi. The pilot will end in May 2006, and NUHPP partners are trying to raise funds for the scaled-up version of the project. The team viewsthe USAID support as instrumental in helping to build the Kenyan research program on urban health and poverty.

The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children

The Council applied again in 2002 to the MCW Partnership Fund to match funds from USAID's West Africa Regional Program mission to support the Ouagadougou Urban Health and Equity Initiative (now

called the Ouagadougou Urban Health and Poverty Initiative), which was established in 2001 to document disparities in urban health. The MCW application was successful, and consequently the PCP3 supported research in Ouagadougou on current malaria care-seeking and home management practices, and a pilot intervention assessing the feasibility of community-based distribution (CBD) of prepackaged therapeutic units of chloroquine and paracetamol for home treatment of presumptive malaria in two neighborhoods of Ouagadougou.

The pilot intervention demonstrated that, with a minimal amount of training, community volunteers can provide quality information to local mothers and, by selling at a symbolic cost, improve the compliance of household treatments and at the same time provide a safe alternative to clinical treatment. Evaluation of the intervention also validated the hypothesis that the CBD strategy was equitable — both affluent and poor households benefited from the project, and no religious or social group was excluded.

These results were presented to the Ministry of Health in 2004 with the goal of advocating for a more comprehensive strategy of urban malaria control.

Both projects in the PCP3 Urban Studies Program were successful in conducting initial research that has improved health professionals' and policymakers' understanding of the health needs of poor urban communities.

The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children

Part of project Number/s: **06609**

Country/ies: Burkina Faso

Technical Coord.: Julia Dayton, Mark Montgomery

Period: September 2002 – December 2003

Objective: To document in two neighborhoods of Ouagadougou the feasibility of interventions to treat malaria in children; to support the development, by officials of the Regional Department of Health and the Ministry of Health, of a comprehensive strategy for urban malaria control.

Activity Description:

Note: This activity is funded by USAID's West African Regional Program and USAID/Washington's Office of Environment and Urban Programs through the Making Cities Work Partnership Fund.

The Ouagadougou Urban Health and Equity initiative is a partnership of l'Unité d'Enseignement et de Recherche en Démographie (UERD) of the University of Ouagadougou, the Population Council, Mwangaza Action, Save the Children Pays-Bas, Direction Regionale de la Santé, and the Centre National de Formation et de Recherche sur le Paludisme. UERD is one of the leading population research institutes in West Africa. With an international team of 12 full-time researchers, its expertise is recognized in three complementary fields: reproductive health, population and development strategies, and women and poverty. Mwangaza Action is a nongovernmental organization in Burkina Faso that specializes in community mobilization and the use of the participatory learning approach to health issues.

The initiative is documenting disparities in urban health and will conduct a controlled trial to measure the impact on child mortality of dual interventions against malaria in randomly selected census enumeration zones of Ouagadougou. The complementary interventions — which include using insecticide-impregnated materials and providing training on appropriate household management of malaria — have proven successful in rural settings.

This activity comprises two preparatory activities for the trial: formative research to characterize current practices for home management of and care seeking for malaria; and a pilot intervention to test the feasibility of community-based social marketing of prepackaged chloroquine for home treatment of malaria in children.

Final Report:

UERD and the National Malaria Research and Training Center (CNRF) of the Ministry of Health conducted an experiment to assess the feasibility of community-based distribution (CBD) of prepackaged therapeutic units (PTU) of chloroquine and paracetamol for home treatment of presumptive malaria. The research was conducted in two distinct and sociologically different neighborhoods of Ouagadougou-Wemtanga and Taabtenga. The intervention focused on children under age seven. A total of 47 neighborhood volunteers were trained by the District Health Team and CNRFP to provide mothers (or other household care-givers) with basic information on appropriate home management of simple malaria in their young children. For the mothers who wished to purchase it, the volunteer sold pre-packaged doses of chloroquine and paracetamol in the age-specific dosages recommended by the National Ministry of Health

of Burkina Faso. UERD conducted baseline and final surveys to assess change in household practices in care-seeking and home management of malaria in young children; follow-up interviews with a sample of clients; focus group discussions and exit interviews outside of health centers and private clinics were also used to assess community views of the intervention.

Sales records and inventory checks showed that a total of 1,779 PTUs where sold in two months (September and October 2003). End line survey results showed that in the two samples, after only two months of operations, 12 percent of children who had fevers in Wemtenga and 17 percent in Taabtenga were treated with PTUs. Two-thirds (65 percent) of the PTUs were administered during the correct amount of days (i.e., three). UERD conducted 124 PTU client interviews less than 10 days after the PTUs were purchased. Client interviews confirmed that none of the children suffered any ill effect from the PTU and that all recovered from their fever. Focus group discussion with PTU users and non-users alike indicated that there is a strong demand for home treatment of uncomplicated fevers at all ages and that the CBD strategy is acceptable despite the fact that the volunteers are not health professionals.

By providing age-specific packets of chloroquine, each with a full course of treatment, the community-based distribution of low cost anti-malarials in prepackaged age-specific therapeutic units was shown to reduce the health risks that stem from current patterns of inappropriate care. The project demonstrated that, with a minimal amount of training, community volunteers can provide quality information to local mothers and by selling at a symbolic cost (approximately 10 cents per PTU), improve the compliance of household treatments and at the same time provide a safe alternative to clinical treatment. The evaluation also validated the hypothesis that the CBD strategy was equitable — both affluent and poor households benefited from the project, and no religious or social group was excluded.

UERD and CNRFP are planning a workshop to present these results to the Ministry of Health and advocate for a comprehensive strategy for urban malaria control. The workshop should increase local understanding of appropriate treatment of simple malaria in children, drawing specific attention to differences in treatment by household wealth.

Implementing Organization(s): Teaching and Research Unit in Demography (UERD) of the University of Ouagadougou (CP03.07A)

Collaborating Organization(s): Mwangaza Action
National Center for Malaria Training and Research
Population Council
Regional Health Office of Ouagadougou
Save the Children Pays-Bas

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

The Nairobi Urban Health and Poverty Project: Clarifying Operational Details of the Experiment

Part of project Number/s: **06609**

Country/ies: Kenya

Technical Coord.: Julia Dayton

Period: January 2002 – December 2002

Objective: To assess the impact of community-based livelihood and health service activities on the health and well-being of residents of four informal settlements in Nairobi; to develop the operational design of this experiment through social and evaluative research on community reactions to various existing programs intended to ameliorate the health and livelihood problems of the urban poor.

Activity Description:

The African Population and Health Research Center (APHRC) is conducting research aimed at documenting the prevalence and severity of poverty-related health problems in the slums of Nairobi and field testing health and livelihood interventions to improve well-being in this setting. The APHRC's Nairobi Urban Health and Poverty project (NUHPP) will test feasible means of alleviating urban health problems and poverty. USAID's Making Cities Work Partnership Fund matched funds with USAID's Office of Population to provide support through the Population Council Program III to develop the research components of the project. The project was conducted by the APHRC in collaboration with the Council's Policy Research Division.

The goal of this activity was to develop the operational specifics of interventions, establish institutional arrangements, and coordinate the full-scale experiment. Interventions will be community-led and will improve health and reproductive health services and behaviors and alleviate poverty in Nairobi slums. One arm of the experiment will configure health service strategies (community organization, outreach, and health promotion), and a second will configure livelihood and economic strategies (community resource mobilization, livelihood, and community development). Together, these strategies imply a four-cell experiment, as the experimental arms can be pursued independently, jointly, or not at all. Work will be undertaken in conjunction with a program of demographic surveillance and social research funded by the Rockefeller Foundation. The project is identifying institutional partners for developing and conducting the two arms of the study. The Program for Appropriate Technology in Health (PATH) and CARE International will join the initiative as service delivery partners. PATH will coordinate the community health components of the project, and CARE will take the lead on the livelihood components. A third partner will be identified to provide support for clinical reproductive health and ambulatory health care components of the project.

Three main field activities were being by the Population Council Program III: (1) an inventory of health facilities, nongovernmental organizations, and community-based organizations operating in the slum communities; (2) an assessment of community perceptions of key livelihood and health intervention priority areas; and (3) an assessment of community reactions to planned interventions.

Final Report:

A needs assessment was conducted in four slum settlements (Kawangware, Korogocho, Njiru, and Viwandani) in which the NUHPP is being carried out. The study involved mapping health, livelihood, and other community facilities; interviewing heads of the facilities; and conducting focus group discussions and

in-depth interviews with residents of the four settlements. Using maps drawn by the Central Bureau of Statistics prior to the 1999 census, fieldworkers surveyed each slum and indicated the physical location of all community facilities and resources available, such as land, water, housing, and sanitary conditions. Interviews were conducted with heads of modern health facilities, traditional health providers, and the staff of community institutions and livelihood initiatives. In order to understand the perspectives of the communities regarding the most critical health problems and general needs confronting them, possible solutions to the problems, the potential role of the communities in dealing with the problems, coping strategies, health-seeking behavior, and experiences with past and existing interventions meant to improve their well-being, 24 focus group discussions and 58 in-depth interviews were conducted throughout the study area. Interviews were conducted mostly with women who bear the primary responsibility for taking care of children younger than five years. Despite the presence of 235 modern and traditional health facilities, the four slum settlements are suffering from inadequate access to basic health care and hence bear an unfair share of morbidity and mortality from largely preventable causes. Adverse health conditions have resulted in community dependence on expensive, private, for-profit facilities that operate informally using ill-trained professionals. Community members cited child health, sanitation, and poor livelihood opportunities as their main health concerns and needs. The needs expressed by health service providers were related to service premises (e.g., expansion and renovation), presence of qualified health personnel or staff training, and technical capabilities (e.g., medical equipment and laboratory facilities).

Because the main aim of the needs assessment was to identify both the opportunities for interventions and possible partners, it was deemed necessary to explore the feasibility of working in these areas. Local institutions were asked to identify challenges they face in working in these communities. Security concerns were cited as a significant challenge according to institutions working in the Korogocho slum (38 percent). While other locations also experienced such concerns, in Korogocho the issue was considered the most important hindrance to working in communities. Lack of financial resources was also cited by all institutions operating in the four informal settlements as well as lack of cooperation, the problem of defaulted fees or loans, and lack of expansion space.

Health and livelihood interventions are being designed based on the findings noted above. The key health components will target those areas identified above as the main causes of observed high infant mortality rates among slum dwellers. Livelihood activities will be implemented to improve household living standards while giving an impetus to the health interventions.

Implementing Organization(s): African Population and Health Research Center (CP01.11A)

Collaborating Organization(s): CARE International
JHPIEGO
Population Council
Program for Appropriate Technology in Health

Activity Funding: Field Support & Special Initiatives Core

Contribution to Results Framework: IR 3.1

ACTIVITY GRID BY COUNTRY

Australia

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women

Bangladesh

Activity	Result	Status	Outcomes
Patterns of Marriage and the Onset of Childbearing in Rural Bangladesh: The Impact of Large-Scale Educational and Livelihood Interventions (part of #05461) ADOL	IR 2.1	Completed	Expanded knowledge of whether, how, and to what extent interventions in areas of adolescent work and education can change marriage and childbearing patterns of girls

Bolivia

Activity	Result	Status	Outcomes
Technical Assistance to the Bolivia Ministry of Health (part of #03200) ECC/MFI	IR 1.2	Completed	Improved quality of family planning and reproductive health services

Brazil

Activity	Result	Status	Outcomes
Home Sampling and Rapid Testing for Reproductive Tract Infections (#05608) NT/RTI	IR 1.3	Completed	Assessment of performance, feasibility, and acceptability of home-based and clinic-based self-sampling, and of rapid testing for RTIs
Audio Computer-Assisted Self-Interviewing (Audio-CASI) to Assess Reporting of Sensitive Behaviors (#05609) NT/RTI	IR 2.1	Completed	Assessment of acceptability, feasibility, and validity of reporting using ACASI compared with face-to-face interviewing as part of a clinical study in Brazil
Technical Assistance to Update National Family Planning Guidelines in Brazil (part of #03200) ECC/MFI	IR 1.2	Completed	Improved access by providers to contraceptive technology updates; improved quality of service delivery; increased and continued use of modern family planning methods

ADOL = Understanding and Meeting the Needs of Adolescents; CD = Contraceptive Development; CFI = Core-Funded Initiatives; ECC/MFI = Expanding Contraceptive Choice and ECC-related Mission-Funded Initiatives; MICROB = Microbicides Program; MFI = Mission-Funded Initiatives (not ECC-related); NT/RTI = New Technologies and Strategies for RTI Interventions; TRANS = Transitions in Reproductive Behavior in the Developing World; URBAN = Urban Studies; XFP = Experimental Family Planning Studies in Rural Africa
Status "Completed" = PCP3-funded scope of work completed. Some activities continued with non-PCP3 funding; for information contact the Council.

Brazil

Activity	Result	Status	Outcomes
The Essentials of Contraceptive Technology—Translation from English to Brazilian Portuguese (#03221) ECC/MFI	IR 1.2	Completed	Improved access to up-to-date contraceptive technology information in Brazil
Contraceptive Technology Internet Web Site for Providers in Brazil: Continued Operation and Maintenance (#03222) ECC/MFI	IR 1.2	Completed	Improved access by providers to contraceptive technology updates; improved information-exchange methods for providers
Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Stage 1 (#03257) ECC/MFI	IR 1.2	Completed	Appropriate service delivery strategies designed by obtaining more accurate information on local reproductive health and family planning needs
Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Project Development Stage (#03264) ECC/MFI	IR 1.2	Completed	Stage 2 activities developed
Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez (#05826) ECC/MFI	IR 1.2	Completed	Reduce STI/HIV/AIDS risk behaviors in vulnerable populations through consistent condom use; improve access to testing, counseling, and treatment; build capacity of local NGO to ensure sustainability of project
Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State) (#05827) ECC/MFI	IR 1.2	Completed	Improved access to condoms, testing, counseling, and prevention information on STI/HIV/AIDS among truck drivers crossing the border in Foz do Iguaçu; ensured access to monitoring and treatment of HIV/AIDS for truck drivers
Technical Assistance for the Implementation of the USAID Brazil Research Strategy on STI/HIV/AIDS in Brazil (#44804) ECC/MFI	IR 2.1	Completed	Development of the USAID/Brazil/MOH STI/HIV/AIDS research strategy by providing technical assistance to BEMFAM and the USAID/MOH Consortium.

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Brazil

Activity	Result	Status	Outcomes
Technical Assistance to Improve the Knowledge and Use of STI/HIV/AIDS Related Services in Vulnerable Groups in Brazil (#44805) ECC/MFI	IR 1.2	Completed	Development and implementation of the USAID(Brazil)/MOH STI/HIV/AIDS research strategy by providing technical assistance to the Brazil MOH.

Burkina Faso

Activity	Result	Status	Outcomes
The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children (part of #06609) URBAN	IR 3.1	Completed	Malaria prevention and treatment strategies in urban areas better understood; health policy informed

Cambodia

Activity	Result	Status	Outcomes
Operations Research Support for USAID/Cambodia's HIV/AIDS and Reproductive and Child Health Program (#05828) MFI	IR 3.1	Completed	Critical programmatic issues identified through application of research leading to operations research design; local partners provided with technical assistance for evaluating service delivery strategies/interventions; improved capacity of national and local organizations to conduct research to design operations research and to use and disseminate findings

Chile

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women
Androgen Implant (#07801) CD	IR 1.1	Completed	Hormonal contraceptive for men
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	PCP3 funding discontinued	Continuous-use contraception for women

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Status "Completed" = PCP3-funded scope of work completed. Some activities continued with non-PCP3 funding; for information contact the Council.

Dominican Republic

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	PCP3 funding discontinued	Continuous-use contraception for women
Strategic Assessment of Reproductive Health Services in the Dominican Republic (#03259) ECC/MFI	IR 1.2	Completed	Groundwork for developing effective strategies to improve reproductive health service-delivery system and reduce unwanted pregnancies, maternal morbidity and mortality, and transmission of HIV and other sexually transmitted infections

East and Southern Africa Region

Activity	Result	Status	Outcomes
Partial Support for Population Council Regional Workshop on Implant Technology: Past Experiences and Perspectives for Africa (#03258) ECC/MFI	IR 1.2	Completed	Information about contraceptive implants and their introduction provided, experience with implants shared, interest gauged, and sites identified for potential introduction of Jadelle®
Institutional Support for Regional Professional Societies: Support for the East, Central, and Southern African Obstetrical and Gynecological Society Fourth International Scientific Conference (#03261) ECC/MFI	IR 1.2	Completed	Support provided to facilitate information exchange among providers, governments, and collaborating agencies
Fact Sheets on Girls' Lives in East and Southern Africa (part of #05400) MFI	IR 2.1	Completed	Create awareness of context of adolescent lives among policymakers through production and dissemination of five fact sheets at local, regional, and international levels

Egypt

Activity	Result	Status	Outcomes
Youth Livelihoods in Egypt (#05405) MFI	IR 2.1	Completed	Improved understanding of youth livelihood opportunities and constraints in Egypt; identification of potential policy and programmatic interventions in this area

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Status "Completed" = PCP3-funded scope of work completed. Some activities continued with non-PCP3 funding; for information contact the Council.

Egypt

Activity	Result	Status	Outcomes
Stalled Fertility Transition in Egypt (#06011) MFI	IR 2.1	Completed	Brief report containing key findings from field survey to be conducted in late 2003 to be submitted to USAID/Cairo; analytical report to be submitted to scientific journal
Confronting Female Genital Cutting: Assessing a Community Intervention in Egypt (#05460) CFI	IR 3.1	Canceled	Assessment of effectiveness of community-based intervention to eradicate FGC in Egypt
The INTACT Network for FGM/C Research and Change (#06500) CFI	IR 2.1	Completed	Expand network of researchers, identify research gaps, advance knowledge in the field of FGC, and provide technical training for NGO leaders working to eliminate FGC

Ethiopia

Activity	Result	Status	Outcomes
Technical Assistance for the Development of a Reproductive Health Strategy in Ethiopia (part of #03200) ECC/MFI	IR 1.2	Completed	Improved quality of care in reproductive health and family planning services
Technical Assistance to Evaluation of the National Norplant® Program of Ethiopia (part of #03200) ECC/MFI	IR 1.2	Completed	Understand current and future role of Norplant in Ethiopia's family planning and reproductive health care system
Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities (part of #03200) ECC/MFI	IR 1.2	Completed	Greater acceptability and use of coital-dependent contraceptive methods by young people; improved access to emergency contraception by young people; improved understanding of and practice of dual protection among young people

Finland

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women

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France

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women

Germany

Activity	Result	Status	Outcomes
Androgen Implant (#07801) CD	IR 1.1	Completed	Hormonal contraceptive for men

Ghana

Activity	Result	Status	Outcomes
Technical Assistance to the Navrongo Community Health and Family Planning Project and the Community-Based Health Planning and Services Initiative (part of #04700) XFP	IR 3.1	Completed	Technical expertise provided to Ghanaian partners to conduct experimental health and family planning research and develop monitoring and evaluation systems for nationwide expansion of experimental research; technical expertise provided to disseminate results from experiment and expansion
The Navrongo Community Health and Family Planning Project (part of #04700) XFP	IR 3.1	Completed	Service activities and community organization and mobilization demonstrated to have impact on primary health care and family planning services use and effectiveness; fertility and mortality reduced
The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project (part of #04700) XFP	IR 3.1	Completed	Proper assessment of demographic impact of CHFP experiment
Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project (part of #06613) XFP	IR 3.1	Completed	Findings from CHFP disseminated to health providers nationwide; efforts at replicating CHFP nationwide informed; information on experiment disseminated to international research community
A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana (part of #04700) XFP	IR 3.1	Completed	Demonstrated reduction of FGC via community organization and action in setting where practice has been nearly universal

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Ghana

Activity	Result	Status	Outcomes
Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy (part of #06613) XFP	IR 3.1	Completed	Impact of nationwide expansion and replication of CHFP informed by development and maintenance of systems to accurately monitor and evaluate CHPS activity
Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative (part of #06613) XFP	IR 3.1	Completed	Nationwide expansion and replication of CHFP informed by counterpart training in CHPS process and sharing technologies; lead district provides guidance to other districts within region for CHPS implementation
Subaward to the University of Cape Coast for Assessing Demographic Impact of the Community-Based Health Planning and Services Initiative (part of #04700) XFP	IR 3.1	Completed	Identify populations that will respond positively to CHPS within study communities; assess attitudes toward and use of health and family planning services

Guatemala

Activity	Result	Status	Outcomes
Technical Assistance for a Preintroduction Study of Norplant® in Guatemala (part of #03200) ECC/MFI	IR 1.2	Completed	Method mix expanded; improved understanding of services as a result of expanding method mix; knowledge gained of acceptability of long-term family planning methods
Technical Assistance to the Guatemala Ministry of Health to Develop a Reproductive Health Needs Assessment Strategy (part of #03200) ECC/MFI	IR 1.2	Completed	Strategy developed to assess reproductive health and family planning service delivery

Honduras

Activity	Result	Status	Outcomes
Technical Assistance to the Honduras Ministry of Health (part of #03200) ECC/MFI	IR 1.2	Completed	Improved access to high-quality reproductive health and family planning services

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India

Activity	Result	Status	Outcomes
Addressing Adolescent Reproductive Health Needs: An In-Depth Study of the Gate Keepers in Uttaranchal (#44504) MFI	IR 3.1	Completed	Findings of formative research will contribute to OR study on reproductive health needs of young men
Completion Activities and Assessment of Findings: Allahabad Project (part of #05461) ADOL	IR 2.1	Completed	Investigate feasibility of providing vocational counseling and training to adolescent girls in urban slum in India; assess impact of these opportunities on girls and their families

Interregional

Activity	Result	Status	Outcomes
The Future Demand for Contraception (part of #04800) TRANS	IR 2.1	Completed	Assessed validity of assumptions underlying existing projections made by UN and The Futures Group; developed new methodology for projecting method mix; prepared new country-level projections to 2015
Analysis of the “Birth Dearth” Hypothesis (part of #04800) TRANS	IR 2.1	Completed	Improved understanding of recent and potential future trends in fertility in the developed and developing world
Analysis of the Causes of Stalling Fertility Transitions (part of #04800) TRANS	IR 2.1	Completed	Improved understanding of recent and potential future trends in fertility in developing world
Variations in Contraceptive Prevalence at the End of the Fertility Transition (part of #04800) TRANS	IR 3.1	Completed	Improved understanding of relationship between contraceptive prevalence and fertility at end of transition

Italy

Activity	Result	Status	Outcomes
Conference to Advance Research on Female Genital Cutting (#04701) XFP	IR 2.1	Completed	Knowledge of FGC practices improved; preliminary network of researchers on FGC established

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Kenya

Activity	Result	Status	Outcomes
Case Studies of Adolescent Livelihood Programs in Kenya (part of #05400) MFI	IR 2.1	Completed	Create awareness and understanding of livelihood programs for adolescents through production of case studies of existing livelihood projects for young women in Kenya
The Reporting of Sensitive Behavior Among Adolescents: A Methodological Experiment in Kenya (part of #05462) ADOL	IR 2.1	Completed	Understanding of degree to which interview context affects adolescents' responses to questions about sexual and other sensitive behaviors
The Nairobi Urban Health and Poverty Project: Clarifying Operational Details of the Experiment (part of #06609) URBAN	IR 3.1	Completed	Field appraisal of existing health and livelihoods activities

Latin America and the Carribean Region

Activity	Result	Status	Outcomes
Institutional Support for Regional Professional Societies: Sponsoring a Symposium on Contraceptive Technology at the 17th Meeting of the Latin American Association of Researchers in Human Reproduction (#03255) ECC/MFI	IR 1.2	Completed	Support provided to facilitate information exchange among providers, governments, and collaborating agencies

Malawi

Activity	Result	Status	Outcomes
The Reporting of Sexual Activity in Malawi (part of #05462) ADOL	IR 2.1	Completed	Understand whether interview context affects young women's responses to questions about premarital sex in Malawi

Mali

Activity	Result	Status	Outcomes
Factors Affecting Contraceptive Use in Mali (part of #04607) MFI	IR 2.1	Completed	Knowledge of trends in contraceptive use, barriers to use, and unmet family planning need increased

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Mali

Activity	Result	Status	Outcomes
Assessment of the Availability and Functioning of Family Planning Services in Mali (part of #04607) MFI	IR 2.1	Completed	Family planning equipment and supply needs determined; recommendations for USAID/Mali's ten-year strategic plan developed
Assessment of the Functioning and Effectiveness of the Community-Based Distribution Programs in Mali (part of #04607) MFI	IR 2.1	Completed	Increased knowledge of CBD program effectiveness
Regional Dissemination of the Family Planning Program Assessment Study Findings in Mali (#04608) MFI	IR 2.1	Completed	Greater coverage by family planning programs; increased use of modern family planning methods in program's catchment areas; recommendations for improved service coverage; adoption of innovations; consistent high level of knowledge among national- and regional-level health staff

Netherlands

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women

Philippines

Activity	Result	Status	Outcomes
Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing (#03507) CFI	IR 3.1	Completed	Better understanding of the effects of quality-of-care interventions on clients' knowledge, contraceptive continuation, and unintended pregnancies.

Senegal

Activity	Result	Status	Outcomes
Evaluation of the National Norplant® Program in Senegal (#03251) ECC/MFI	IR 1.2	Completed	Improved understanding of acceptability of Norplant®; improved understanding of reasons for loss to follow-up; recommendations for improving national contraceptive implant services

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Senegal

Activity	Result	Status	Outcomes
Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing (#03507) CFI	IR 3.1	Completed	Better understanding of the effects of quality-of-care interventions on clients' knowledge, contraceptive continuation, and unintended pregnancies.

South Africa

Activity	Result	Status	Outcomes
IPD: Phase 1 Safety Study of Carraguard® (PC-515) Among HIV-Positive Women and Men (#05603) MICROB	IR 1.3	Completed	Assessment of safety and acceptability of Carraguard® among HIV-positive women and men, including safety when applied directly to penis, and effect on HIV shedding in vagina
Technical Assistance for the Council's Expanded Safety Study Assessing the Safety, Acceptability, and Preliminary Effectiveness of the Council's Lead Candidate Microbicide, Carraguard® (PC-515) (#05601) MICROB	IR 1.3	Completed	Development of standard operating procedure for monitoring Phase 2 trial and site-specific procedures for ongoing quality assurance (QA) during Phase 2 trial; QA audit helped prepare laboratory for transition from Phase 2 to Phase 3 effectiveness trial
IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard® (#05604) MICROB	IR 1.3	Completed	Readiness for Phase 3 trial, including increased capacity at Phase 2 sites, development of informed consent materials, and transparency via community consultation with community advisory groups (CAGs), as appropriate
IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard® (#05607) MICROB	IR 1.3	Completed	Determine efficacy of Carraguard® in preventing HIV seroconversion in women
CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard® (part of #08300) MICROB	IR 1.3	Completed	Determine efficacy of Carraguard® in preventing HIV seroconversion in women
Reproductive Tract Infection Sampling Study (#05605) NT/RTI	IR 1.3	Completed	Assessment of performance, feasibility, and acceptability of clinic-based self-sampling; determination of prevalence of HPV subtypes in Phase 3 trial community

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South Africa

Activity	Result	Status	Outcomes
Home Sampling and Rapid Testing for Reproductive Tract Infections (#05608) NT/RTI	IR 1.3	Completed	Assessment of performance, feasibility, and acceptability of home-based and clinic-based self-sampling, and of rapid testing for RTIs
Transition to Adulthood in the Context of AIDS in South Africa (part of #05462) ADOL	IR 2.1	Completed	Augmented knowledge of key transitions in lives of adolescents residing in volatile, high-risk environments and of impact of life-skills programs on adolescent risky sexual behavior

United States

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethynylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Completed	User-controlled long-acting vaginal contraceptive for women
Nestorone® (NES) Implant (#07703) CD	IR 1.1	Completed	Long-term contraceptive method for lactating women
Nestorone® (NES), Not Method-Specific (#07600) CD	IR 1.1	Completed	Pharmacology, metabolism, and toxicology data on all methods delivering NES; synthesis and formulation of NES; radioimmunoassay of clinical blood samples
Androgen Implant (#07801) CD	IR 1.1	Completed	Hormonal contraceptive for men
Androgen, Not Method-Specific (#12400) CD	IR 1.1	Completed	Pharmacology, metabolism, and toxicology data on all methods delivering MENT™
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	PCP3 funding discontinued	Continuous-use contraception for women
Lonidamine Analogs (#08510) CD	IR 1.1	Completed	Novel male hormonal contraceptive
Norplant® (#07701) CD	IR 1.1	Completed	Extension of use-life to seven years

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United States

Activity	Result	Status	Outcomes
Jadelle® (Two-Rod Levonorgestrel Implant System) (#07702) CD	IR 1.1	Completed	Extension of use-life to five years
CBR: Gel Production for Safety Study of Carraguard® Among HIV-Positive Women and Men (part of #08300) MICROB	IR 1.3	Completed	Applicators containing Carraguard and methyl cellulose placebo produced and shipped for use in Phase I safety study among HIV-positive women and men in Durban, South Africa
IPD: Phase 1 Safety Study of Carraguard® for Rectal Use (#05606) MICROB	IR 1.3	Activity placed on indefinite hold	Assessment of safety and acceptability of Carraguard® when used rectally
CBR: Reproductive Toxicology: Segment I and Segment II for Carraguard® (part of #08300) MICROB	IR 1.3	Completed	Evaluation of Carraguard® for potential in causing abnormal embryonic development during organogenesis and toxicity potential on maternal and embryo/fetus during the time course of test formulation dosing
CBR: Phase 3 Documentation and Production Start-Up (part of #08300) MICROB	IR 1.3	Completed	FDA and EAEMP approval of Phase 3 CMC documentation, allowing for commencement of Phase 3 gel production
CBR: Carraguard® and Placebo Production for Phase 3 Efficacy Trial (part of #08300) MICROB	IR 1.3	Completed	Carraguard and placebo applicators provided for Phase 3 clinical trials; stability profiles, chemical and pharmacokinetic analysis, and other evaluations carried out to satisfy FDA-requested testing
CBR: Stability Profiles for Carraguard® and Methyl Cellulose Placebo (part of #08300) MICROB	IR 1.3	Completed	Establish five-year stability profile for Carraguard to enhance registration as OTC product and to minimize final product pricing; establish long-term stability profile for methyl cellulose to ensure stability and usability through Phase 3 clinical trial
CBR: Rectal Safety of OTC Lubricants (part of #08300) MICROB	IR 1.3	Completed	Identify OTC lubricants that put user at less risk for infection by HIV and other sexually transmitted pathogens when used rectally
Development of Microbicide/Spermicide Containing Lignosulfonic Acid (LSA) (part of #08300) MICROB	IR 1.3	Completed	Worked to establish baseline toxicology and stability profiles of the LSA/carrageenan/N-9 formulation

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United States

Activity	Result	Status	Outcomes
CBR: Development of a Nonsurfactant Contraceptive Microbicide (part of #08300) MICROB	IR 1.3	PCP3 funding discontinued	Development of safe and effective contraceptive microbicide
CBR: Preclinical Studies for Second-Generation Microbicides (part of #08300) MICROB	IR 1.3	Completed	Establish foundation for preclinical file and position PC-710 for clinical safety studies
CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds (part of #08300) MICROB	IR 1.3	Completed	Development of safe, stable, and effective combination microbicide
CBR: Blocking DC–Virus Spread with Carrageenan-Based Agents (part of #08300) MICROB	IR 1.3	Completed	Effectiveness of carrageenan-based agents in blocking virus capture and transmission by DCs in vitro evaluated; evaluation of ability of carrageenan-based approaches to prevent vaginal transmission of virus to monkeys begun.
Studies in Family Planning (#02800) CFI	IR 2.1	Completed	Two issues of Studies in Family Planning

West and Central Africa Region

Activity	Result	Status	Outcomes
Launching the Regional Francophone MAQ Subcommittee (part of #03200) ECC/MFI	IR 1.2	Completed	To design and implement interventions for improving access to and quality of family planning/reproductive health services in Francophone Africa
Technical Assistance to the Francophone MAQ Subcommittee to Develop Activities in West and Central Africa (part of #03200) ECC/MFI	IR 1.2	Completed	Use mandate of Francophone MAQ Subcommittee to design appropriate activities and studies within region

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West and Central Africa Region

Activity	Result	Status	Outcomes
Institutional Support for Regional Professional Societies: Plenary Session on Female Condoms: Introduction and Access at the 8th International Society of Women and AIDS in Africa Conference (#03256) ECC/MFI	IR 1.2	Completed	Support provided to facilitate information exchange among providers, governments, and collaborating agencies

Zambia

Activity	Result	Status	Outcomes
Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two (#03253) ECC/MFI	IR 1.2	Completed	Better understanding of improvements in quality of care and impact of expanded contraceptive method introduction on quality of family planning services.
Expanding Contraceptive Choice Demonstration Project in the Copperbelt Province of Zambia: Transition Phase (#03254) ECC/MFI	IR 1.2	Completed	Enhance contraceptive choice and quality of care nationwide
From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt (#03262) ECC/MFI	IR 1.2	Completed	Improved service delivery mechanisms; improved method availability and acceptability; improved provider competence; increased client satisfaction; greater contraceptive choice
Technical Assistance to the Zambia Ministry of Health for the Development of a National Reproductive Health Strategy (part of #03200) ECC/MFI	IR 1.2	Completed	Registration of injectable contraceptives and emergency contraception pills in Zambia
Searching for Synergies: Dual Protection Within the Context of Provider-Dependent Contraception (#03265) ECC/MFI	IR 3.1	Completed	Formulate a series of practical, evidence-based recommendations to assist programs in promoting DP among family planning clients.

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Zambia

Activity	Result	Status	Outcomes
Reducing Unwanted Pregnancy Among Victims of Sexual Assault: New Windows of Opportunity for Emergency Contraception (#44103) ECC/MFI	IR 2.1	Completed	Provided information relevant to the scaling up of emergency contraception services in Zambia
Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing (#03507) CFI	IR 3.1	Completed	Better understanding of the effects of quality-of-care interventions on clients' knowledge, contraceptive continuation, and unintended pregnancies.

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